Errata Slip

Changes in Drugs and Devices Notices of Judgment Nos. 326-425.

Page 163, last paragraph, line 3, change falsey to falsely.

Page 186, N. J. No. 376, next to last paragraph, line 3, delete comma after Kansas.

Page 208, Products Index, column 2, change San-Vak to San-Yak.

FEDERAL SECURITY AGENCY

DRUGS AND DEVICES

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

851–900

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*
Washington, D. C., March 10, 1944.

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

851. Misbranding of Tescum Powders. U. S. v. Edna B. Brown (Tescum Company). Plea of guilty. Fine, $100 and costs. (F. D. C. No. 6476. Sample No. 59339–E.)

On November 11, 1942, the United States attorney for the Northern District of Ohio filed an information against Mrs. Edna B. Brown, trading as the Tescum Company, Cleveland, Ohio, alleging shipment on or about March 12, 1941, of a quantity of Tescum Powders from the State of Ohio into the State of West Virginia.

Analysis of a sample of Tescum Powders showed each power to contain 0.56 grain tartar emetic, 2.12 grains ammonium chloride, a trace of a gold compound, and sugar.

The article was alleged to be misbranded in that the statement, "Tescum Powders Tends to discourage drinking," appearing on the labeling was false and misleading as the drug would not be efficacious to discourage addiction to the use of alcoholic liquors. It was alleged to be further misbranded in that it contained tartar emetic and would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, "One powder twice a day in any food or liquid."

On October 30, 1942, a plea of guilty having been entered, the court imposed a fine of $100 and costs.

* For omission of accurate statement of quantity of contents, see Nos. 854, 876, 884, 896, 898; omission of, or unsatisfactory, ingredients statements, Nos. 854, 866, 873, 884, 891, 895, 896, 898, 899; inconspicuousness of required label information, Nos. 864, 871; deceptive packaging, Nos. 873; filth, No. 861; failure to comply with official compendium packaging requirements, No. 862.

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852. Adulteration and misbranding of Leunbach' Paste. U. S. v. Merz & Company Chemical Works, Inc., and Adolph G. Schickert. Plea of guilty by Adolph G. Schickert, sentence 18 months in jail. Plea of nolo contendere by corporation. Sentence suspended. (F. D. C. No. 5505. Sample Nos. 5032–E, 5033–E, 12877–E, 14055–E to 14057–E, incl., 14059–E, 20127–E, 28933–E, 28934–E, 32419–E, 32420–E, 32473–E to 32475–E, incl., 33525–E.)

On October 31, 1941, the United States attorney for the District of New Jersey filed an information against Merz & Company Chemical Works, Inc., East Orange, N. J., and Adolph G. Schickert, alleging shipment within the period from on or about March 16, 1939, to on or about September 11, 1940, from the State of New Jersey into the States of Ohio, Georgia, California, Pennsylvania, and the District of Columbia, of quantities of Leunbach' Paste complete outfit and Leunbach' Paste refill tubes which were misbranded. On March 31, 1942, the grand jury for the District of New Jersey presented an indictment based on the same charges against the defendants. (The information which had been filed on October 31, 1941, was dismissed at the conclusion of the case.)

Examination showed that the Leunbach' Paste complete outfit contained a tube of paste and instruments for its application, and the refill tubes contained the same paste. Analysis of a sample of this paste showed that it contained potassium iodide, small proportions of thymol, benzoin, and myrrh incorporated in a soap base, alcohol, and water.

Portions of the article were alleged to be adulterated in that its purity fell below that which it purported and was represented to possess, in that the article by virtue of the use for which it was recommended and the conditions under which it was to be used, that is, injection into the cervix and pregnant uterus under conditions of the strictest asepsis, purported and was represented to be sterile, whereas it was not sterile but was contaminated with viable microorganisms.

All of the shipments were alleged to be misbranded in that the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling. (The labeling of this product is set out substantially in Drugs and Devices Notices of Judgment No. 607.)

It was alleged to be further misbranded in that its labeling was false and misleading in its representations and suggestions that it was a safe and appropriate treatment for the therapeutic termination of pregnancy, whereas it was not a safe and appropriate treatment for the therapeutic termination of pregnancy, but was unsafe and dangerous, and capable of producing serious and even fatal consequences.

On October 14, 1942, Adolph Schickert entered a plea of guilty, and a plea of nolo contendere was entered on behalf of the corporation. On October 30, 1942, the court sentenced Schickert to serve 6 months on each of the 17 counts in the indictment, the periods imposed on the first 3 counts to be served consecutively, totaling 18 months, and the periods imposed on the remainder of the counts to be served concurrently with that imposed on count 1. On November 6, 1942, the court ordered sentence suspended as to the corporation.

853. Misbranding of Hunt's Salve. U. S. v. 5½ Dozen Packages of Hunt's Salve. Default decree of condemnation. Product ordered destroyed. (F. D. C. No. 7829. Sample No. 94230–E.)

On June 29, 1942, the United States attorney for the Eastern District of Arkansas filed a libel at Little Rock, Ark., against 5½ dozen packages of Hunt's Salve, alleging that the article was shipped in interstate commerce on or about May 5, 1942, by the Allied Drug Products Co. from Chattanooga, Tenn. The article was labeled in part: "Hunt's Salve Manufactured for A. B. Richards Med. Co. Sherman, Texas."

Examination showed that the article consisted essentially of chrysarobin 0.43 percent, sulfur iodine, and carbolic acid, in an ointment base. The amount of ointment contained in each can did not exceed 1¼ avoirdupois ounces.

The article was alleged to be misbranded (1) in that it would be dangerous to health when used as recommended: "Once or twice a day and always at bed time, apply Hunt's Salve; rub it in thoroughly"; (2) in that the statement, "Contents: 1½ oz. av.," was false and misleading since the actual amount of ointment did not exceed 1¼ avoirdupois ounces; and (3) in that the statements in the labeling representing and suggesting that the article would be effective to relieve itching and remove crusts associated with eczema, promote the healing of cuts, burns, scratches, and skin abrasions, and would give relief from itching caused by skin irritations, were false and misleading as the article was not effective for these purposes.

On October 2, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

854. Misbranding of Indian Antiseptic Hair and Scalp Stimulator. Adulteration and misbranding of Eez-all Germicide for the Skin. U. S. v. Adolph F. Frick. Plea of nolo contendere. Fine, $300. (F. D. C. No. 6441. Sample Nos. 22596-E, 22597-E.)

On April 1, 1942, the United States attorney for the Northern District of California filed an information against Adolph F. Frick, San Francisco, Calif., alleging shipment on or about April 3, 1941, of a quantity of the above-named products from the State of California into the State of Nevada.

Analysis of a sample of Indian Antiseptic Hair and Scalp Stimulator showed that it consisted essentially of small proportions of a phenolic compound and free ammonia, alcohol, and water.

The article was alleged to be misbranded in that the statements, "Indian * * * Hair and Scalp Stimulator for dandruff—itching scalp—falling hair—eczema, etc. * * * For itching scalp, dandruff, falling hair, eczematous condition," and the designs of an Indian head, arrows, and Indian scenes appearing on the label, were false and misleading since they represented and suggested that the article consisted solely of substances used by the Indians, and that it would be efficacious as a hair and scalp stimulator, in the treatment of dandruff, itching scalp, falling hair, eczema, and other eczematous conditions, whereas it contained ingredients unknown to the Indians and would not be efficacious for the conditions represented.

It was alleged to be misbranded further in that it was in package form and the label did not bear an accurate statement of the quantity of contents. It was also misbranded in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient.

Analysis of a sample of Eez-all Germicide for the Skin showed that it consisted essentially of small proportions of a phenolic compound and free ammonia, alcohol, and water. Bacteriological examination showed that the article was neither an antiseptic nor a germicide. The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, and in that it purported and was represented to be a germicide, whereas it was not a germicide. It was alleged to be misbranded (1) in that the statement, "Eez-all Germicide for the Skin For Cuts, Bruises, Burns, Itching, Poison Oak, Athlete's Foot, Throat, and Gums," was false and misleading as it represented that the article would bring about ease and relief from pain and discomfort, implied in the expression "Eez-all," and that it was a germicide and effective for the conditions mentioned, whereas the drug was not a germicide and was not effective for the conditions indicated; (2) in that it was fabricated from two or more ingredients and its label did not bear the common name or usual name of each active ingredient; and (3) in that its label did not bear adequate directions for use.

On October 17, 1942, after entry of a plea of nolo contendere, the defendant was fined $100 on each of the 3 counts contained in the information.

855. Misbranding of Ru-Ma-Dol, McDades Prescription, Moe-Pep, and Allan's Red Wash. Adulteration and misbranding of Allan's Gland Capsules. U. S. v. Allan & Co., Inc., and John G. Ayars. Plea of nolo contendere. Fine, $150. (F. D. C. No. 7298. Sample Nos. 67928-E, 67932-E, 71214-E, 71216-E, 71217-E.)

On October 2, 1942, the United States attorney for the Eastern District of Missouri filed an information against Allan & Co., Inc., St. Louis, Mo., and John G. Ayars, alleging shipment on or about September 18, 20, and 27, and October 1, 1941, from the State of Missouri into the States of Arkansas and Tennessee of quantities of the above named products.

Analysis of a sample of Ru-Ma-Dol showed that it consisted essentially of sodium salicylate and extracts of plant drugs, including an alkaloid-bearing drug, alcohol, glycerine, and water. The article was alleged to be misbranded in that statements in the labeling regarding the efficacy of the drug in the cure, mitigation, treatment, or prevention of rheumatism, neuralgia, neuritis, pain, and swelling, and in the relief of symptoms of rheumatism, neuralgia, and neuritis, were false and misleading, since the product was not efficacious for these purposes.

Examination of a sample of McDades Prescription showed that it consisted essentially of extracts of plant drugs, including a laxative drug and a bitter drug, glycerine, alcohol, and water. The article was alleged to be misbranded in that the statement on the labeling, "Vegetable Alterative An aid in the relief of pain and discomfort arising from certain Rheumatism and Catarrhal affections," was false and misleading, as it was not efficacious for the purpose represented and suggested. It was further misbranded in that its label failed to bear adequate directions for use, since the directions did not limit the duration of administration of the drug.

Analysis of a sample of Moe-Pep showed that it consisted essentially of extracts of plant drugs, including nux vomica and a laxative drug, a small proportion of an arsenic compound, sugars, alcohol, and water. The article was alleged to be misbranded in that the name, "Moe-Pep," was misleading, as it represented and suggested that the drug would give the user more pep, whereas it would not give the user more pep. The article was also misbranded in that the statement, "Sexual Power Stimulant For men or women suffering from low sexual power not due to any disease, nor to natural frigidity, but to overwork, worry or advancing years; up to a reasonable age. * * * until desired results are obtained * * * Should you experience too much stimulation, * * *," were false and misleading, since the drug would not be effective for these purposes. It was further misbranded in that the label failed to warn that not more than the recommended dosage should be taken since the drug contained strychnine and arsenic compound, that frequent, continued, or prolonged use of the drug might result in serious injury, and that use of the drug by elderly persons might be especially dangerous.

Examination of a sample of Gland Capsules showed that it consistedly essentially of an extract of nux vomica, extracts of organic material, and small proportions of an arsenic compound, an iodine compound, and zinc phosphide. The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, as it was represented to contain zinc sulfide, whereas, it did not contain zinc sulfide. It was alleged to be misbranded in that the following and similar statements appearing on the labeling, "Gland Capsules Each Capsule contains: * * * Zinc Sulphide * * * Sexual Power Stimulant For men or women suffering from low sexual power not due to any disease nor to natural frigidity, but to overwork, worry or advancing years. * * * until desired results are obtained. * * * Should you experience too much stimulation * * * If results are not satisfactory your Physician should be consulted," were false and misleading, as the product did not contain zinc sulfide and was not efficacious for the purposes recommended. The article was further misbranded in that its labeling did not bear adequate warning against its use, where such use might be dangerous to health, or against unsafe dosage or methods of duration of administration. The article contained nux vomica and arsenic, and its label failed to warn that not more than the recommended dosage should be taken, that frequent continued or prolonged use might result in serious injury, and that its use by elderly persons might be especially dangerous.

A sample of Allan's Red Wash Combination was found to be composed of a bottle of "Red Wash" and a bottle of "Sa-Ura Emulsion." Analysis of a sample of the "Red Wash" showed that it consisted essentially of small proportions of cresol, boric acid, compounds of aluminum, ammonium and zinc sulfates, glycerine, and water. The "Sa-Ura Emulsion" consisted essentially of castor oil and volatile oils, including sandalwood, turpentine, and balsam of copaiba. The circular accompanying the drug carried the following statements: "While this treatment is rational and well known and will probably give you satisfaction, it should be regarded as an emergency treatment. Then as soon as possible you should see your Doctor and have a thorough Biological examination made. What are commonly termed social diseases are not to be regarded lightly. If infected, in fairness to your family and your fellow citizens, submit to early biological examination that general infection may be checked and controlled." The article was alleged to be misbranded in that the quoted statements were false and misleading, as they represented that the drug would be efficacious in the cure, mitigation, treatment, or prevention of social diseases, whereas it was not efficacious for this purpose.

On December 3, 1942, a plea of nolo contendere having been entered, a fine of $15 on each of the 6 counts in the information was imposed upon the corporation, and a fine of $10 on each of the 6 counts was imposed upon the individual defendant.

856. Adulteration and misbranding of cascara compound tablets and Pentabisarsen ampuls. U. S. v. Max Gold and Irving Levine (Gold Leaf Pharmacal Co.). Plea of guilty. Fine, $500 on counts 2 and 4. Sentence suspended and defendants placed on probation for 1 year on counts 1 and 3. (F. D. C. No. 6466. Sample Nos. 69921–E, 69925–E.)

Both products were below their own standard. In addition, the cascara compound tablets did not bear adequate directions for use or warning statements.

On October 2, 1942, the United States attorney for the Southern District of New York filed an information against Max Gold and Irving Levine, trading as the Gold Leaf Pharmacal Co., New Rochelle, N. Y., alleging shipments of cascara compound tablets and of Pentabisarsen ampuls on or about May 9 to 12, 1941, from the State of New York into the State of Connecticut.

Analysis of a sample of the cascara compound tablets showed that they contained no strychnine sulfate, but did contain alkaloids of belladonna, aloin, podophyllin, and extracts of plant drugs, including ginger, and a laxative drug.

The article was alleged to be misbranded in that the statements on the label represented that each tablet contained 1/60 grain of strychnine sulfate, whereas it did not contain any strychnine sulfate. It was further misbranded in that the extract of belladonna, a constituent of the drug, contained the alkaloids atropine, hyoscine, and hyoscyamine, and the label failed to bear the name and quantity or proportion of those alkaloids. The article was also misbranded in that the labeling failed to bear adequate warnings against use by children and by persons in those pathological conditions wherein use of the drug may be dangerous to health; against unsafe dosage, or methods or duration of administration, or application in such manner and form as are necessary for the protection of users; and in that it did not bear warnings that the preparation should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent or continued use may result in dependence on laxatives.

The article was alleged to be adulterated in that its strength differed from and its purity and quality fell below that which it purported and was represented to possess, since it was represented to contain strychnine sulfate, but contained no strychnine sulfate.

Analysis of a sample of Pentabisarsen ampuls showed that the solution contained 1.28 percent of bismuth and 0.311 percent of arsenic.

It was alleged to be misbranded in that the statements appearing on the label representing the drug to contain 2 percent solution of sodium bismuth pentavalent, and organic ester of arsonic acid containing approximately 36 percent bismuth and 13 percent arsenic, were false and misleading as the quantities of said elements, based upon the standard so declared, were thus represented to be not more than 0.72 percent of bismuth and not more than 0.26 percent of arsenic, whereas the drug contained more bismuth and arsenic than declared.

The Pentabisarsen ampuls were also alleged to be adulterated in that their strength differed from and their purity and quality fell below that which they were represented and purported to possess.

On October 14, 1942, the defendants entered a plea of guilty and were fined $250 on counts 2 and 4 of the information, a total fine of $500. Imposition of sentence was suspended on counts 1 and 3, and each of the defendants was placed on probation for a period of 1 year.

857. Misbranding of Mrs. Price's special prepared boric acid. U. S. v. 92 Packages of Mrs. Price's Special Prepared Boric Acid. Default decree of condemnation and destruction. (F. D. C. No. 8974. Sample No. 22616–F.)

On December 11, 1942, the United States attorney for the Middle District of Pennsylvania filed a libel against the above-named product at Harrisburg, Pa., alleging that the article had been shipped in interstate commerce on or about September 16, 1942, by Mrs. W. T. Price under the designation Price Compound Co., from Minneapolis, Minn.; and charging that it was misbranded in that it was sold under a name recognized in the United States Pharmacopoeia, and purported to be and was represented as an antiseptic, and its labeling failed to bear adequate directions for use.

The article was also alleged to be misbranded under the provisions of the act applicable to foods, reported in F. N. J. No. 4489.

On February 12, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

858. Misbranding of citrate of magnesia. U. S. v. 99 Cases of Citrate of Magnesia. Consent decree of condemnation. Product ordered released under bond for relabeling. (F. D. C. No. 7399. Sample Nos. 40679–E, 40680–E.)

On April 27, 1942, the United States attorney for the Eastern District of Pennsylvania filed a libel at Philadelphia, Pa., against 99 cases of citrate of magnesia. On June 22, and September 18, 1942, amendments to the libel were filed. It was alleged in the libel as so amended that the product had been shipped by the United States Pharmacal Co. from Newark, N. J., on or about June 24, 1941.

The article was alleged to be misbranded (1) in that the labeling failed to bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, since it failed to warn that the article was not to be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present; and (2) in that the labeling failed to bear adequate warning against unsafe methods or duration of administration, since it failed to warn that frequent or continued use of the preparation might result in dependence on laxatives.

On September 18, 1942, Benly Products Company, Philadelphia, Pa., claimant, having admitted the allegations of the libel and having consented to the entry of a decree, judgment of condemnation was entered and it was ordered that the product be released under bond for relabeling.

859. Misbranding of "Q–T." U. S. v. 35 Packages and 23 Packages of "Q–T." Default decrees of condemnation. Product ordered destroyed. (F. D. C. No. 8269. Sample Nos. 21719–F, 21720–F.)

On August 31 and October 14, 1942, the United States attorney for the Western District of Pennsylvania filed libels at Pittsburgh, Pa., against 23 4-ounce bottles, and 35 2-ounce bottles of "Q-T," alleging that the article had been shipped in interstate commerce on or about May 22 and July 4, 1942, by the Allied Pharmacal Co. from Cleveland, Ohio. The article was labeled in part: "Q-T For Adults Only, Contains Gold and Sodium Chloride and Ammonium Chloride. * * * This preparation was formerly called Quits."

Examination of a sample of the article showed that it contained 0.16 grain of gold and sodium chloride per fluid ounce, and 6.3 grains of ammonium chloride per fluid ounce.

The article was alleged to be misbranded in that the labeling failed to bear adequate directions for use since it did not state the conditions for which the article was to be used.

On October 19, 1942, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

860. Adulteration and misbranding of phenobarbital tablets. U. S. v. The Physicians' Chemical and Drug Co. and Melvin L. Berger. Plea of not guilty by the corporation. Verdict of guilty. Fine, $500. Case against Melvin L. Berger dismissed. (F. D. C. No. 7233. Sample No. 72204–E.)

On or about October 15, 1942, the United States attorney for the Northern District of Illinois filed an information against the Physicians' Chemical and Drug Co., Chicago, Ill., and Melvin L. Berger, alleging shipment on or about October 8, 1941, from the State of Illinois into the State of California of a quantity of phenobarbital tablets. The tablets were labeled in part: "Phenobarbital ½," and "Phenobarbital-Gr. ½."

The article was alleged to be misbranded in that the label statements represented and suggested that each tablet contained not more than ½ grain of phenobarbital, whereas each tablet contained not less than 0.58 grain of phenobarbital.

It was also alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in the National Formulary, its strength differed from the standard set forth in that compendium, and its difference in strength was not plainly stated on the label. The National Formulary provides that "Tablets of Phenobarbital contain not more than 107.5 percent of the labeled amount of phenobarbital for tablets of more than 0.07 Gm.,—and not more than 109 percent for tablets of 0.07 Gm. or less, including all tolerances." In this case each tablet contained not less than 116 percent of the labeled amount of phenobarbital.

*See also Nos. 852, 854–856.

On March 26, 1943, the case came on for trial before the court without a jury. The corporation was found guilty, and the court imposed a fine of $500. On motion of the defendants the action against the individual defendant was dismissed by the court.

861. Adulteration and misbranding of triple distilled water. U. S. v. Kenneth Gaylord Ziegler (Ziegler Pharmacal Co.). Plea of guilty. Fine, $450. (F. D. C. No. 6418. Sample Nos. 46751–E, 57061–E.)

On April 20, 1942, the United States attorney for the Western District of New York filed an information against Kenneth Gaylord Ziegler, trading as Ziegler Pharmacal Co., Buffalo, N. Y., alleging shipment of a quantity of triple distilled water on or about March 6 and September 4, 1941, from the State of New York into the State of Missouri and the Territory of Puerto Rico.

Analyses of a sample of the article from the shipment made into the State of Missouri showed that the product was not sterile and that it contained viable mold micro-organisms.

The article was alleged to be adulterated in that it was a drug the name of which is recognized in the National Formulary, and its quality and purity fell below the standard set forth in that compendium since the ampuls did not contain sterile redistilled water, but contained water that was contaminated with viable mold. It was further adulterated in that it consisted in whole or in part of a filthy substance.

Examination of a sample taken from the shipment into Puerto Rico showed that the average net contents was less than 10 cc. per ampul, namely, 9.25 cc. per ampul. The article was not a clear liquid since some of the ampuls examined contained solid particles. The article did not meet the test for oxidizable substances in that when it was treated according to the test laid down in the National Formulary the color of the liquid disappeared in less than 10 minutes when 0.2 cc. of twentieth-normal potassium permanganate was added, indicating that the article contained oxidizable substances in excess of the maximum tolerance permitted by the National Formulary.

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in the National Formulary, and its quality and purity fell below the standard set forth in that compendium and its difference in quality and purity from such standard was not stated on the label.

It was alleged to be misbranded in that the statement, "10 cc. Plus," borne on the label was false and misleading as each of the ampuls contained materially less than 10 cc. of the drug.

On November 23, 1942, a plea of guilty having been entered, the court imposed a fine of $150 on each of the 3 counts of the information.

862. Adulteration and misbranding of triple distilled water. U. S. v. Diarsenol Company, Inc. Plea of guilty. Fine, $500. (F. D. C. No. 6507. Sample Nos. 11275–E to 11277–E, incl.)

This product failed to conform to the requirements of the National Formulary.

On July 13, 1942, the United States attorney for the Western District of New York filed an information against the Diarsenol Company, Inc., Buffalo, N. Y., alleging shipment from on or about March 29 to May 22, 1941, from the State of New York into the State of Texas of quantities of ampuls of triple distilled water.

Analysis of a sample of the product showed that it did not comply with the requirements of the National Formulary for purity in that the hydrogen-ion concentration was above pH 7.0. It was found also that 14 percent of the ampuls did not contain the quantity of contents declared on the label, nor did it meet the National Formulary requirements for fill of 10-cc. ampuls, since 40 percent of the ampuls contained less than 10.50 cc. of liquid. Tests conducted on the ampuls themselves showed that the glass failed to comply with the National Formulary requirements for ampul glass. In addition, another portion was found not to comply with the National Formulary requirements for triple distilled water in that it contained excessive oxidizable substances.

The article was alleged to be adulterated in that it purported to be and was represented as a drug recognized in the National Formulary and its quality fell below the standard set forth in that compendium since it contained a hydrogen-ion concentration of more than pH 7.0, which digression from the standard was not plainly stated on the label. The article in the said two lots was alleged to be misbranded (1) in that the statement "10 cc." shown on the

label was false and misleading since each of the ampuls contained a less amount; (2) in that it was not packaged as prescribed in the National Formulary, since the glass used for the ampuls did not pass the test for solubility and reaction required by that compendium; and (3) in that the ampuls did not contain the excess volume (0.5 cc.) which the National Formulary requires should be measured into ampuls purporting to contain a 10-cc. dose of a mobile solution. One of the shipments was alleged to be adulterated in that it fell below the standard set forth in the National Formulary, since it contained an excess of oxidizable substances, and this fact was not plainly stated on its label.

On October 26, 1942, a plea of guilty having been entered, the court imposed a fine of $100 on each of the 5 counts in the information.

863. Adulteration and misbranding of tincture of iron and elixir of iron, quinine and strychnine. U. S. v. L. Perrigo Company. Plea of nolo contendere. Fine, $150. (F. D. C. No. 7699. Sample Nos. 47545–E, 47547–E, 66255–E.)

On November 13, 1942, the United States attorney for the Western District of Michigan filed an information against L. Perrigo Co., a corporation, Allegan, Mich., alleging shipment of quantities of the above-named products on or about March 6 and May 2, 1941, from the State of Michigan into the State of Indiana.

The United States Pharmacopoeia provides that tincture of iron shall contain an amount of ferric chloride corresponding to not less than 4.5 grams of iron. Analysis of a sample of Tincture Iron U. S. P. showed that it contained an amount of ferric chloride corresponding to not more than 3.15 grams of iron per 100 cc. The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, and its strength differed from and its quality fell below the standard set forth in that compendium as the drug contained ferric chloride corresponding to not more than 3.15 grams of iron per 100 cc. It was alleged to be misbranded in that the statement, "Tincture Iron U. S. P.," appearing on the label was false and misleading when applied to a drug which did not conform to the requirements of the United States Pharmacopoeia.

A drug compounded in accordance with the formula for elixir of iron, quinine and strychnine set forth in the National Formulary must contain an amount of ferric citrochloride equivalent to not less than 5.60 grams of iron per 1,000 cc., and must contain not less than 8 grams of quinine hydrochloride per 1,000 cc. Examination of a sample from each of 2 shipments of Elixir Iron, Quinine and Strychnine, N. F., showed that the article in one shipment contained an amount of ferric citrochloride equivalent to not more than 2.80 grams of iron per 1,000 cc., and not more than 4.90 grams of quinine hydrochloride per 1,000 cc. A sample from the second shipment contained not less than 9.5 grams of quinine hydrochloride per 1,000 cc. The article was alleged to be adulterated in that it purported to be and was represented as a product recognized in the National Formulary and its strength differed from and its quality fell below the standard set forth in such compendium. It was alleged to be misbranded in that the statement, "Elixir Iron, Quinine and Strychnine, N. F.," appearing on the label was false and misleading when applied to an article which did not conform to the requirements of the National Formulary.

On November 30, 1942, a plea of nolo contendere having been entered, the court found the defendant guilty and assessed a fine of $25 on each count, or a total of $150.

864. Adulteration and misbranding of Real's Antiseptic Medicated Skin Cream, aromatic spirit of ammonia, and sweet spirit of nitre. U. S. v. Baker Drug Corp. Plea of guilty. Imposition of sentence suspended for 3 years on condition that the defendant would not violate the Food, Drug, and Cosmetic Act and would pay a fine of $200 under the Probation Statute. (F. D. C. No. 7746. Sample Nos. 78865–E, 87895–E, 87896–E.)

On November 18, 1942, the United States attorney for the Eastern District of Virginia filed an information against the Baker Drug Corporation, Norfolk, Va., alleging shipment of quantities of the above-named products on or about February 12 and March 21, 1942, from the State of .Virginia into the States of Pennsylvania and North Carolina. The former shipment was made in the name of Jos. Friedberg.

Analysis of a sample of Real's Antiseptic Medicated Skin Cream showed the product to consist essentially of small proportions of potassium hydroxide, volatile oils, including menthol, eucalyptol, and oil of bergamont, and a trace of phenol, incorporated in a base of stearic acid, petrolatum, and beeswax. Bacteriological examination showed the article to be devoid of antiseptic properties.

The article was alleged to be adulterated in that it was represented as an antiseptic and its strength differed from and its quality fell below that which it purported and was represented to possess, since it was not antiseptic. It was alleged to be misbranded in that the statement, "Antiseptic," borne on the labeling was false and misleading since the drug was not an antiseptic.

Examination of a sample of aromatic spirit of ammonia showed that the product did not conform to the specifications in the United States Pharmacopoeia in that there was a very material excess of ammonia. The article was alleged to be adulterated in that it purported and was represented to be a drug the name of which is recognized in the United States Pharmacopoeia, and its strength differed from the standard set forth in that compendium, since it contained not less than 2.95 grams of total ammonia in each 100 cc. and not more than 58.2 percent of alcohol, whereas the United States Pharmacopoeia provides that aromatic spirit of ammonia shall contain not more than 2.1 grams of total ammonia in each 100 cc. and not less than 62 percent of alcohol by volume. The article was alleged to be misbranded in that the name and address of the manufacturer appearing on the label was not placed with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use; it was in very small type and, in some instances, illegible.

Analysis of a sample of sweet spirit of nitre showed that the product did not conform to the specifications in the United States Pharmacopoeia in that there were varying shortages of ethyl nitrite in the various units examined. The article was adulterated in that it purported and was represented to be a drug recognized in the United States Pharmacopoeia, and its strength differed from the standard set forth in that compendium since it contained ethyl nitrite in amounts ranging from 0.77 to 2.09 percent, and its specific gravity was 0.8347 at 25° Centigrade, whereas the United States Pharmacopoeia provides that sweet spirit of nitre shall contain not less than 3.5 percent of ethyl nitrite, and that its specific gravity shall be not more than 0.823 at 25° Centigrade.

It was alleged to be misbranded in that the name and address of the manufacturer was inconspicuously placed on the label; it was in very small type and, in some instances, illegible.

On November 30, 1942, after a plea of guilty was entered, the court suspended the imposition of sentence for a period of 3 years, upon the condition that the defendant would not violate the Food, Drug, and Cosmetic Act and would pay a fine of $200 under the probation statute.

865. Adulteration and misbranding of medical carbon dioxide and medical carbon dioxide and oxygen mixture. U. S. v. The Liquid Carbonic Corporation (Wall Chemicals Division of the Liquid Carbonic Corporation). Plea of guilty. Fine, $200. (F. D. C. No. 7705. Sample Nos. 91275-E, 91276-E.)

On October 15, 1942, the United States attorney for the Northern District of Illinois filed an information against the Liquid Carbonic Corporation, trading at Chicago, Ill., under the name of the Wall Chemicals Division of the Liquid Carbonic Corporation, alleging shipment on or about March 12 and April 2, 1942. of quantities of the above-named products from the State of Illinois into the State of Wisconsin.

The medical carbon dioxide was alleged to be adulterated (1) in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the standard set forth in that compendium since it had a pronounced odor, whereas carbon dioxide, which conforms with the description and possesses the physical properties set forth in the United States Pharmacopoeia. is an odorless gas; and (2) in that a substance, nitric oxide, had been mixed with it so as to reduce its quality.

It was alleged to be misbranded in that the statements, "The purity of the contents of this cylinder has been determined and recorded. It conforms to the approved specifications for this gas * * *," appearing on the tag, were false and misleading since it contained an impurity, nitric oxide, and did not conform to the approved specifications for carbon dioxide gas.

The carbon dioxide and oxygen mixture was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, since it was represented to contain 5 percent of carbon dioxide, whereas it contained not more than 3 percent of carbon dioxide.

It was alleged to be misbranded in that the statement, "5 percent Carbon Dioxide," borne on the labeling was false and misleading when applied to a drug that contained not more than 3.4 percent of carbon dioxide.

On December 22, 1942, a plea of guilty having been entered, the court imposed a fine of $50 on each count, or a total of $200.

866. Adulteration and misbranding of medical carbon dioxide. U. S. v. 4 Cylinders of Medical Carbon Dioxide. Default decree of condemnation. Product ordered destroyed. (F. D. C. No. 7527. Sample No. 91275–E.)

On May 18, 1942, the United States attorney for the Eastern District of Wisconsin filed a libel at Milwaukee, Wis., against 4 cylinders of medical carbon dioxide, alleging that the article had been shipped on or about March 12, 1942, by Wall Chemicals Division of the Liquid Carbonic Corp., from Chicago, Ill.

Carbon dioxide is an article described in the United States Pharmacopoeia as an odorless gas. Examination of the gas contained in the cylinders showed that it had a pronounced odor which was due to nitric oxide.

The article was alleged to be adultered in that it purported to be a drug the name of which was recognized in an official compendium, but its quality or purity fell below the standard set forth in such compendium. It was also adulterated in that the article was a drug, and a substance, nitric oxide, had been mixed with it so as to reduce its quality.

The article was alleged to be misbranded in that the following statements appearing on the tag attached to the cylinder were false and misleading as applied to an article that did not conform to the approved specifications for such gas: "The Purity of the contents of this cylinder has been determined and recorded. It conforms to the approved specifications for this gas * * *."

On October 8, 1942, no claimant having appeared, decree of condemnation was entered and the product was ordered destroyed.

867. Adulteration and misbranding of sutures. U. S. v. 684 Tubes of Surgical Sutures. Default decree of condemnation. Product ordered destroyed. (F. D. C. No. 8151. Sample No. 74663–E.)

On August 17, 1942, the United States attorney for the Eastern District of New York filed a libel at Brooklyn, N. Y., against 684 tubes of surgical sutures, alleging that the article had been shipped in interstate commerce on or about March 28, 1942, by W. J. Prendergast from Chicago, Ill. The article was labeled in part: "Davis Surgical Gut U. S. P. C Medium Chromic (20-Day) Boilable 277 2."

Examination showed that the sutures were not sterile, but were contaminated with living aerobic spore-bearing bacilli.

The article was alleged to be adulterated in that it purported and was represented to be a drug recognized in the United States Pharmacopoeia and its purity fell below the standard set forth in such compendium, since the article was not sterile.

The article was alleged to be misbranded in that the statement in the labeling, "Guaranty Davis Sutures are guaranteed sterile," was false and misleading since the article was not sterile.

On October 26, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

868. Adulteration and misbranding of sutures. U. S. v. 1,092 Sutures. Default decree of condemnation and destruction. (F. D. C. No. 7398. Sample No. 84939–E.)

Examination of this product showed it to be contaminated with viable spore-bearing bacteria.

On April 27, 1942, the United States attorney for the Eastern District of New York filed a libel against 1,092 sutures at Brooklyn, N. Y., alleging that the article had been shipped in interstate commerce on or about March 23, 1942, by W. J. Prendergast Co. from Chicago, Ill.; and charging that it was adulterated and misbranded. The article was labeled in part "Davis Sutures Surgical Gut U. S. P. * * * Davis Sutures Inc. Chicago."

The article was alleged to be adulterated in that it purported to be and was represented as a drug, surgical gut, the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the standard set forth in that compendium since the article was not sterile.

It was alleged to be misbranded in that the two statements, (carton) "Surgical Gut U. S. P.," and (leaflet) "Davis Sutures are guaranteed sterile, and to remain sterile until tubes are opened," were false and misleading since the article did not

conform to the requirements of the United States Pharmacopoeia for surgical gut and the sutures were not sterile.

On August 14, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

869. Adulteration of absorbent cotton. U. S. v. 2,500 Cartons of Absorbent Cotton. Consent decree of condemnation. Product ordered released under bond to be reprocessed. (F. D. C. No. 7535. Sample No. 87171–E.)

The quality and purity of this product fell below the pharmacopoeial standard since it contained less than 60 percent of fibers 12.5 mm. or greater in length, and more than 10 percent of fibers 6.25 mm. or less in length, and was not white and had not been freed from adhering impurities, but contained hulls, shells, oil spots, and gray streaks.

On May 21, 1942, the United States attorney for the District of Columbia filed a libel against 2,500 cartons of absorbent cotton at Washington, D. C., alleging that the article had been shipped in interstate commerce on or about April 6, 1942, by Acme Cotton Products Co. Inc., from Dayville, Conn.; and charging that it was adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the standard set forth therein. It was labeled in part: "Grade A Absorbent Cotton."

On October 22, 1942, the Acme Cotton Products Co., Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be reprocessed under the supervision of the Food and Drug Administration.

870. Adulteration of absorbent cotton. U. S. v. 80 Cartons of Absorbent Cotton. Consent decree of condemnation. Product ordered released under bond for reprocessing and resterilizing. (F. D. C. No. 8156. Sample No. 24108–F.)

On August 18, 1942, the United States attorney for the District of Columbia filed a libel against 80 cartons, each containing 50 1-pound packages, of absorbent cotton at Washington, D. C., alleging that the article had been shipped in interstate commerce on or about July 20, 1942, by the Seamless Rubber Co., Valley Park, Mo.; and charging that it was adulterated. The article was labeled in part: "Absorbent Cotton U. S. P. Standard."

The article was alleged to be adulterated in that it purported to be and was represented as a drug, absorbent cotton, the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the standard set forth in that compendium since it had not been freed from adhering impurities, but was contaminated with cotton plant tissues, leaf fragments, and seed coat fragments; whereas the United States Pharmacopoeia states that absorbent cotton shall be freed from adhering impurities.

On July 6, 1943, the Seamless Rubber Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and it was ordered that the product be released under bond, conditioned that it be reprocessed under the supervision of the Food and Drug Administration.

871. Adulteration and misbranding of colloidum ipecacuanha, colloidum belladonna, Lloydrastis. U. S. v. Lloyd Bros., Pharmacists, Inc. Plea of guilty. Fine, $400. (F. D. C. No. 7671. Sample Nos. 72234–E, 73014–E, 80378–E, 80379–E.)

On September 15, 1942, the United States attorney for the Southern District of Ohio filed an information against Lloyd Bros., Pharmacists, Inc., Cincinnati, Ohio, alleging shipment on or about October 24 and December 12, 1941, and January 31 and February 7, 1942, from the State of Ohio into the States of Indiana, California, and Missouri, of quantities of the above-named products.

Analysis of a sample of colloidum ipecacuanha, showed that it contained not less than 1.32 percent of the ether soluble alkaloids of ipecac. The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, that is, not more than 1 percent of the ether soluble alkaloids of ipecac, whereas it contained 1.32 percent of the either soluble alkaloids of ipecac. The article was alleged to be misbranded (1) in that the statement, "Standardized to contain one percent ether soluble alkaloids," appearing on the label was false and misleading as applied to a drug that contained not less than 1.32 percent of ether-soluble alkaloids of ipecac; and (2) in that the statement, "Ipecacuanha * * * Not U. S. P. One-half the drug strength of the official product," appearing on the label, was misleading, as the drug was more than one-half the strength of fluidextract of ipecac as defined and described in the United States Pharmacopoeia.

Analysis of a sample of Lloydrastis showed the article to contain not more than 0.029 percent of hydrastine. The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess in that it was represented to contain 0.08 percent of hydrastine, whereas it contained not more than 0.029 percent of hydrastine. The article was alleged to be misbranded in that the statement on the labeling, "It is standardized to an hydrastine content of .08 percent," was false and misleading as applied to an article that contained a smaller amount of hydrastine.

Analysis of samples from two shipments of colloidum belladonna showed that one contained not less than 0.517 percent of the total alkaloids of belladonna, and the other contained not less than 0.57 percent of the total alkaloids of belladonna. The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess. The article was represented to be standardized to contain not more than .45 percent of the total alkaloids of belladonna root, but in both instances it contained more of the total alkaloids of belladonna root than the amount declared. It was also alleged to be misbranded in that the statement on the label, "Standardized to contain .45 percent total alkaloids," was false and misleading as applied to an article containing a higher percentage of the total alkaloids. It was further alleged to be misbranded in that the statement appearing on the label "Colloidum Belladonna * * * Not U. S. P. Same drug strength as Fluid Extract," was false and misleading, since the drug yielded not less than 0.57 gram of the alkaloids of belladonna root per 100 cc. in the sample from one shipment, and not less than 0.525 gram of the alkaloids of belladonna root per 100 cc. in the sample from the second shipment, whereas the United States Pharmacopoeia provides that "Fluidextract of Belladonna Root yields from each 100 cc., * * * not more than 0.495 Gm. of the alkaloids of belladonna root."

On October 8, 1942, a plea of guilty having been entered, the court imposed a fine of $50 on each of the 8 counts of the information, making a total fine of $400.

872. Misbranding of thiamin chloride tablets, A and D vitamin concentrate tablets, and Valtiva. U. S. v. Harlow B. Boyle and Charles E. Boyle (Boyle & Co.). Pleas of nolo contendere. Each defendant fined $100 on 1 count. Imposition of sentence suspended on remaining counts for 1 year, to become permanent at the end of 1 year in event of no further violation. (F. D. C. No. 5545. Sample Nos. 32972–E, 32973–E, 53348–E.)

These thiamin chloride tablets and the A and D vitamin concentrate tablets fell below their declared potency; and the thiamin chloride tablets and another product, Valtiva, bore misleading curative and therapeutic claims.

On August 10, 1942, the United States attorney for the Southern District of California filed an information against Harlow B. Boyle and Charles E. Boyle, copartners trading as Boyle & Co., Los Angeles, Calif., alleging shipments on or about November 15 and December 9, 1940, and May 12, 1941, from the State of California into the State of Arizona of quantities of the above-named products which were misbranded.

The thiamin chloride tablets were alleged to be misbranded (1) in that the statement, "Thiamin Chloride 1.0 Mgm. Vitamin B_1 333 International Units per tablet," borne on the bottle label was false and misleading since each tablet contained less than 1 milligram, namely, .06 milligram of thiamin chloride, the equivalent of not more than 200 International Units of vitamin B_1; and (2) in that the statement "Lack of Vitamin B_1 may result in retarded growth, malnutrition, loss of appetite, constipation, and certain other abnormal conditions," borne on the label was misleading since it represented and suggested and created in the minds of the readers the impression that retarded growth, malnutrition, loss of appetite, constipation, and the other abnormal conditions suggested by the statement are commonly caused by lack of vitamin B_1, and that readers might reasonably expect to obtain benefit from the use of the article in the treatment of such conditions; whereas such conditions are rarely caused by lack of vitamin B_1, and readers might not reasonably expect to obtain benefit from the use of the article in their treatment since it would not ordinarily be efficacious for such purposes.

The A and D vitamin concentrate tablets were alleged to be misbranded (1) in that the statement, "Each Tablet Contains: Vitamin A—6250 U. S. P. Units, Vitamin D—625 U. S. P. Units," borne on the bottle label and carton was false and misleading since each tablet contained not more than 140 U. S. P. units of vitamin A and not more than 300 U. S. P. units of vitamin D; (2) in that the statement, "Each Boyle A and D tablet supplies 1½ times the minimum daily adult requirement and twice the minimum daily requirement for children, of

vitamin A, and 1½ times the minimum daily requirement of vitamin D for both adults and children," borne on the carton was false and misleading since each tablet would supply less than one-tenth the amount of vitamin A required daily by an infant, and less than one-twenty-fifth the amount of vitamin A required daily by a person 12 or more years of age, and would supply less than three-fourths the amount of vitamin D required daily by any person irrespective of age; and (3) in that the statement "Each tablet is equal in vitamin potency and therapeutic effect to about 2 teaspoonfuls of U. S. P. cod liver oil," borne on the carton was false and misleading since the statement represented that each tablet contained the vitamin potency equivalent in therapeutic effectiveness to about 2 teaspoonfuls of cod liver oil, which would be approximately 6,200 U. S. P. units of vitamin A and not less than 620 U. S. P. units of vitamin D, whereas each tablet contained not more than 140 U. S. P. units of vitamin A, and not more than 300 U. S. P. Units of vitamin D.

The Valtiva was alleged to be misbranded in that the statements "Latest scientific research tells us that at times lack of sufficient dietary intake of vitamins results in run down conditions in the system, such as certain nervous disorders, skin troubles, loss of appetite, loss of weight, indigestion, constipation, susceptibility to colds or infection and general weakness. * * * Valtiva is * * * rich in essential health-building vitamins," appearing in the labeling were misleading in that they represented and suggested and created the impression in the minds of the readers that nervous disorders, skin troubles, loss of appetite, loss of weight, indigestion, constipation, susceptibility to colds or infection, general weakness, and ill health, are commonly caused by the lack of the vitamins A, B_1, G, and D contained in such article, and that readers might reasonably expect to obtain benefit from the use of the article in the treatment of such conditions, whereas these conditions are rarely caused by lack of vitamins A, B_1, G and D, and readers might not reasonably expect to obtain benefit from the use of the article in the treatment of such conditions since it would not ordinarily be efficacious for such purposes.

On December 19, 1942, pleas of nolo contendere having been entered by the defendants, the court imposed a fine of $100 on the count charging misbranding of the thiamin chloride tablets, and suspended imposition of sentence on the counts charging misbranding of the remaining products, such suspension to be permanent after 1 year in the event of no further violations of the law by the defendants.

873. Adulteration and misbranding of citrate of magnesia with magnesium sulfate and misbranding of Pitcher's Castoria. U. S. v. Roma Extract Co., Inc., and Vincenzo Contrino. Plea of guilty. Fine, $50. (F. D. C. No. 7300. Sample Nos. 51685-E, 75662-E, 90417-E.)

On September 10, 1942, the United States attorney for the District of Massachusetts filed an information against the Roma Extract Co., Inc., Boston, Mass., and Vincenzo Contrino. It was alleged in the information that the defendants, within the period from on or about September 23, 1940, to January 11, 1941, sold and delivered to the Hanover Sales Co., Inc., of Boston, Mass., various consignments of Castoria; that at the time of the sale and delivery the defendants in each instance furnished to the Hanover Sales Co., Inc., an invoice containing a guaranty that the article was not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act; that on or about April 28, 1941, the holder of the guaranty introduced and delivered for introduction into interstate commerce a quantity of the said Castoria from Boston, Mass., to Manchester, N. H.; that the guaranties delivered by the defendants were false since the product, when sold and delivered by the defendants and introduced and delivered for introduction into interstate commerce by the holder of the guaranty, was misbranded. The information further alleged that on or about September 11 and November 10, 1941, the defendants shipped from Boston, Mass., into the State of Rhode Island a quantity of a product known as "Citrate of Magnesia with Magnesia Sulphate," which was adulterated and misbranded, and a quantity of Castoria which was misbranded.

Analysis of a sample of the Castoria showed that it consisted essentially of small proportions of Rochelle salt, sodium bicarbonate, extracts of plant drugs, including senna and wormseed, and sugar and water, flavored with aromatics, including methyl salicylate.

The Castoria was alleged to be misbranded in that the statements appearing in the labeling which represented that it was a reliable remedy for worms and diarrhea due to constipation, and would promote sleep by overcoming these

disorders, were false and misleading since it was not effective for such purposes. The Castoria was alleged to be misbranded further in that its label failed to bear the common or usual name of each active ingredient, and in that its container was so made, formed, and filled as to be misleading since the carton was materially larger than necessary to contain the bottles.

The "Effervescing Solution of Citrate of Magnesia with Magnesia Sulphate" was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, since its labeling represented and suggested that it consisted of a solution of magnesium citrate to which magnesium sulfate had been added, whereas it did not so consist but was predominantly a solution of Epsom salts with a small proportion of magnesium citrate. It was alleged to be misbranded in that the statement "Effervescing Solution of Citrate of Magnesia with Magnesia Sulphate," borne on the label was false and misleading since the article was predominantly a solution of Epsom salts with a small proportion of magnesium citrate, and not a solution of magnesium citrate to which magnesium sulfate had been added.

On October 27, 1942, a plea of guilty having been entered, each defendant was fined $25.

874. Adulteration and misbranding of Gold Bond Liquid Hog Medicine. U. S. v. Abraham Bartlet Carlsen (Mid-West Distributors). Plea of guilty. Fine, $25. (F. D. C. No. 7674. Sample No. 73036–E.)

On October 20, 1942, the United States attorney for the Northern District of Iowa filed an information against Abraham Bartlet Carlsen, trading as Mid-West Distibutors, Sioux City, Iowa, alleging shipment on or about November 3, 1941, from the State of Iowa into the State of Nebraska of a quantity of the above-named product.

Analysis of a sample of the Gold Bond Liquid Hog Medicine showed the product to consist essentially of sodium sulfate, hydroxide, and carbonate; iron and copper sulfates, carbonates, creosote, and water, and small amounts of plant material containing .55 percent fluidextract of nux vomica, less than .03 percent potassium iodide, namely 0.001 percent potassium iodide, and less than 9 percent potassium arsenite, namely not more than 0.05 percent potassium arsenite.

It was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, 4 percent of fluid extract of nux vomica, 0.03 percent of potassium iodide, and 9 percent of potassium arsenite, and it did not contain the stated amount of these ingredients.

It was misbranded in that the quantitative statement of ingredients in the labeling was false and misleading as applied to an article that contained smaller amounts of the above-mentioned ingredients.

It was further misbranded in that the statements on the label which represented and suggested that the drug would be efficacious in the treatment of sick hogs and would keep hogs well, were false and misleading, as the drug would not be efficacious for these purposes.

On October 20, 1942, a plea of guilty having been entered, the court imposed a fine of $25.

875. Adulteration and misbranding of first aid bandage. U. S. v. 11½ Dozen Packages of Sterilastic First Aid Bandage. Consent decree of condemnation and destruction. (F. D. C. No. 7834. Sample No. 89775–E.)

This product was not sterile but was contaminated with living micro-organisms.

On June 30, 1942, the United States attorney for the Southern District of New York filed a libel against the above-described product at New York, N. Y., alleging that the article had been shipped in interstate commerce on or about May 25, 1942, by Surgical Dressings, Inc., from Boston, Mass.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess since the name "Sterilastic" implied that it was sterile, whereas it was not sterile.

It was alleged to be misbranded in that the following statement on the label, "Sterilastic * * * The gauze supplied with the Sterilastic may be used in any emergency," was false and misleading since it represented and suggested that the article was sterile and might be used in emergency first-aid injuries, whereas it was not sterile but was contaminated with living micro-organisms.

On December 5, 1942, Surgical Dressings, Inc., claimant, having consented to the entry of a decree, judgment was entered ordering that the product be condemned and destroyed, and that the answer theretofore filed by the claimant be stricken from the record.

876. Adulteration and misbranding of first aid kits. U. S. v. 236 packages of White Cross All Purpose First Aid Kit. Consent decree of condemnation. Product ordered released for relabeling and replacement of unsterile gauze and adhesive bandages. (F. D. C. No. 7405. Sample No. 89176-E.)

On April 28, 1942, the United States attorney for the District of Connecticut filed a libel at Hartford, Conn., against 236 packages of the above-named product, alleging that the article had been shipped in interstate commerce on or about March 16, 1942, by the American White Cross Laboratories, Inc., from New Rochelle, New York. The article was labeled in part: "White Cross All Purpose First Aid Kit." Each kit contained, among other things, a package labeled "Sterilized White Cross Surgical Gauze" and a number of envelopes of adhesive strips.

Bacteriological tests on samples from this consignment showed that the gauze and adhesive strips were not sterile but were contaminated with viable aerobic and anaerobic or facultative anaerobic micro-organisms.

It was alleged to be adulterated in that the purity and quality of the surgical gauze fell below that which it was represented to possess, since the article was not sterile but was contaminated with living micro-organisms.

The article was alleged to be misbranded in that the statement, "First Aid Kit," was false and misleading when applied to an article that was not sterile. It was further misbranded in that the outside container, which was the retail package, did not bear an accurate statement of the quantity of contents.

On November 9, 1942, the American White Cross Laboratories, Inc., having appeared as claimant, judgment of condemnation was entered and the product was ordered released under bond so that it could be relabeled and the surgical gauze and adhesive bandages be replaced by sterile gauze and sterile bandages.

877. Adulteration and misbranding of vitamin A, B_1, D, G capsules. U. S. v. 35 Dozen Bottles of Hyde Brand Vitamins A, B_1, D, G Capsules. Default decree of condemnation and destruction. (F. D. C. No. 7812. Sample No. 54955-E.)

On June 26, 1942, the United States attorney for the Middle District of Pennsylvania filed a libel against the above-named product at Northumberland, Pa., alleging that the article had been shipped in interstate commerce on or about April 18, 1942, by McCambridge and McCambridge Co., from Washington, D. C.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess since it contained not more than 750 U. S. P. units of vitamin D per capsule.

It was alleged to be misbranded in that the statement on the label, "Each capsule contains not less than * * * 1000 U. S. P. Units of Vitamin D," was false as applied to an article that contained not more than 750 such units of vitamin D per capsule. It was alleged to be misbranded further in that the prominent display of the letter "G" in the name of the article, "Vitamin * * * G Capsules," was misleading since the statement represented and suggested that the article contained consequential amounts of Vitamin G, whereas it did not. It was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods reported in F. N. J. No. 4700.

On August 26, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

878. Adulteration and misbranding of "Be" Plex vitamin B-complex with minerals and Iron. U. S. v. 14 Cases of "Be" Plex Vitamin B-Complex With Minerals and Iron. Default decree of condemnation and destruction. (F. D. C. No. 7523. Sample No. 71436-E.)

On May 18, 1942, the United States attorney for the Eastern District of Missouri filed a libel against 12 1-pint bottles of the above-named product at St. Louis, Mo. On November 7, 1942, the libel was amended to change the amount to 14 cases, each containing 12 1-pint bottles, of the said product. It was alleged in the libel as amended that the article had been shipped in interstate commerce on or about January 9, 1942, by the Hale Drug Co. from Birmingham, Ala.; and charged that it was adulterated and misbranded.

Examination of the article showed that it contained not more than 25 percent of the vitamin B_1 content declared on the label.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented on the label to possess, namely, 660 International Units of vitamin B_1 per fluid ounce.

It was alleged to be misbranded in that the following statements in the labeling, "Valuable (in cases of vitamin deficiency) as an aid to promote

appetite and in protecting the body from nerve disorder," and "Indicated in certain cases of retarded growth, constipation, migraine headaches, and helpful promotion of greater vigor, functional digestion and wholesomeness of the skin," were false and misleading in that they represented that the article was valuable as an aid in promoting appetite and protecting the body from nerve disorder, and was of value in retarded growth, constipation, and migraine headaches, and in promoting greater vigor, functional digestion, and wholesomeness of the skin, whereas it would not be efficacious for such purposes.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to food reported in notices of judgment on foods.

On January 16, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

879. Adulteration and misbranding of Vi-Penta drops. U. S. v. Hoffman-La Roche, Inc. Plea of nolo contendere. Fine, $250 on count 1. Imposition of sentence suspended on remaining 15 counts. (F. D. C. No. 7656. Sample Nos. 56804–E, 69145–E, 74168–E, 89116–E.)

On September 4, 1942, the United States attorney for the District of New Jersey filed an information against Hoffman-La Roche, Inc., Nutley, N. J., alleging shipment of Vi-Penta drops within the period from on or about March 18, 1941, to January 15, 1942, from the State of New Jersey into the State of New York. The article was labeled in part: "Each 0.6 cc. (approximately 10 minims) equals 1 Vi-Penta Perle and contains Vitamins: A . . . 9,000 (or "4,000") U. S. P. Units."

Examination of samples taken from each of the 3 shipments labeled as containing 9,000 U. S. P. Units of Vitamin A per 0.6 cc. showed the presence of not more than 2,700, 4,500 and 4,500 U. S. P. Units of Vitamin A, respectively, per 0.6 cc. The shipment labeled as containing 4,000 U. S. P. Units of Vitamin A per 0.6 cc. contained not more than 2,000 Units of Vitamin A per 0.6 cc.

Portions of the article were alleged to be misbranded in that the statements in the labeling which represented and suggested that it was efficacious to bring about normal growth and development of infants and children; that it was efficacious in the cure, mitigation, treatment, or prevention of malnutrition, lowered resistance, and rundown states, and for use during prolonged illnesses such as infections, anemias, tuberculosis, and typhoid; that it was efficacious in the treatment of gastro-intestinal conditions such as diarrhea and colitis, and for use when restrictions in diet become necessary, as in obesity, diabetes, and catarrhal jaundice, and whenever the total food intake must be increased as in hyperthyroid conditions; that it was efficacious in the cure, mitigation, treatment, or prevention of skin diseases such as eczema, for certain allergic conditions such as those due to milk, eggs, and wheat, and for temporary or persistent vomiting, especially during infancy, childhood, and pregnancy; and that it was efficacious as a prophylaxis or treatment of abnormal dentition, or gum and tooth conditions were false and misleading since the article was not efficacious for the conditions indicated.

All shipments of the article were alleged to be adulterated and misbranded in that its strength differed from and its quality fell below that which it purported and was represented to possess, and the labeling was false and misleading since it was represented to contain 9,000 (or 4,000) U. S. P. units of vitamin A per 0.6 cc., whereas it contained in each 0.6 cc. less than the declared amount of vitamin A.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On November 6, 1942, a plea of nolo contendere having been entered, a fine of $250 was imposed on the first count of the information and imposition of sentence was suspended on the remaining 15 counts.

880. Misbranding of prophylactics. U. S. v. 41 Gross of Midgets. Default decree of condemnation. Product ordered destroyed. (F. D. C. No. 7985. Sample No. 16834–F.)

This product purported to be a prophylactic, but would not be effective for such purpose because it contained holes.

On July 25, 1942, the United States attorney for the Southern District of New York filed a libel against 41 gross of an article labeled in part: "Midgets the Short Cap Type Sheath," at New York, N. Y., alleging that the article had been shipped in interstate commerce on or about July 10, 1942, by the Rubber Research Products Corporation from Jersey City, N. J.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess, since it contained holes and was not suitable for use as a prophylactic.

It was alleged to be misbranded in that the following statements in the labeling, "Notice: The enclosed sheath has been 'Water Tested' by expanding, under water pressure, to at least ten times its normal capacity—then examined closely for any detectable leak," were false and misleading, since such statements represented and suggested that the article was free from defect, whereas it was not.

On August 24, 1942, no claimant having appeared, judgment of condemnation was entered and it was ordered that the product be cut up and disposed of as scrap rubber.

881. Adulteration and misbranding of collodion. U. S. v. 1,476 Bottles, 6,000 Bottles, and 2,738 Bottles of Collodion U. S. P. Default decrees of condemnation. Portions of product ordered destroyed; remainder (2,738 bottles) ordered delivered to the Food and Drug Administration. (F. D. C. Nos. 8043, 8076, 8270. Sample Nos. 5255–F, 6202–F, 9339–F.)

On August 1, 10, and 28, 1942, the United States attorneys for the Eastern District of Missouri, the Southern District of Ohio, and the Western District of Texas filed libels against 1,476 bottles of collodion at St. Louis, Mo., 6,000 bottles of collodion at Columbus, Ohio, and 2,738 bottles of collodion at San Antonio, Tex., alleging that the article had been shipped in interstate commerce within the period from June 11 to July 18, 1942, by the Conray Products Co., Inc., from New York, N. Y.; and charging that it was adulterated and misbranded. The article was labeled in part: "Collodion U. S. P.," or "Conray 1 oz. Collodion U. S. P."

The article was alleged to be adulterated in that a mixture containing an ester such as amyl acetate had been substituted for collodion U. S. P.

It was alleged to be misbranded in that the statement "Collodion U. S. P." was false and misleading since it did not have the composition specified by the United States Pharmacopoeia for collodion.

On November 19 and December 24, 1942, no claimant having appeared, judgment of condemnation was entered and 7,476 bottles of the product were ordered destroyed. On October 23, 1942, no claimant having appeared, the court ordered that a default decree of condemnation be entered and the lot located at San Antonio, Tex., delivered to the Food and Drug Administration.

882. Adulteration of cocoa butter. U. S. v. 35 Dozen Packages of Miami Cocoa Butter. Default decree of condemnation. Product ordered rendered for use in war purposes. (F. D. C. No. 8172. Sample No. 4721–F.)

On August 20, 1942, the United States attorney for the Southern District of Ohio filed a libel against 35 dozen packages of Miami cocoa butter at Cincinnati, Ohio, which had been shipped in interstate commerce on or about August 4, 1942, alleging that the article had been shipped by Hampden Sales Association, Inc., from New York, N. Y.; and charging that it was adulterated.

Analysis of a sample showed that it contained approximately 44 percent of some material other than cocoa butter, such as paraffin or petrolatum.

The article was alleged to be adulterated in that a substance other than cocoa butter, i. e. paraffin and petrolatum, had been substituted in part for the article, and had been mixed and packed therewith so as to reduce its quality.

On November 18, 1942, no claimant having appeared, judgment of condemnation was entered and it was ordered that the cocoa butter be delivered to a rendering firm for recovering the fats and oils for war purposes.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

HUMAN USE

883. Action to restrain interstate shipment of a misbranded device known as "Magnetic Ray Appliance" and "Magnetic Ray Instrument". U. S. v. Frank B. Moran (Magnetic Ray Co.). Permanent injunction granted. (Inj. No. 19.)

This device consisted of an electric appliance which would produce a magnetic field. It was accompanied by labeling which recommended its application to various parts of the body and represented that it would be of value in the

*See also Nos. 851–856, incl., 860–868, incl., 871–881, incl.

treatment of many disease conditions. Its physical properties are described in the court's "Findings of Fact."

On May 13, 1942, the United States attorney for the Northern District of Texas filed a complaint against Frank B. Moran, trading as The Magnetic Ray Co., at Dallas, Tex., alleging that the defendant, for several months past, and more particularly since May 1, 1940, up to and including the time of the filing of the complaint, had been introducing or delivering for introduction into interstate commerce or causing such introduction or delivery for introduction into interstate commerce a certain device under the names "Magnetic Ray Appliance" and "Magnetic Ray Instrument"; that accompanying each unit of the device were certain circulars or folders entitled "Directions for Taking Magnetic Ray Treatments," and "Magnetic Rays," respectively, which contained statements which represented that it would produce a powerful, penetrating ray which would prevent and relieve human ills, restore and preserve health, and fight disease; that the rays so produced would prevent "auto-toxemia" due to faulty elimination of poisons, or absorption of poison into the blood from sluggish or constipated intestines, infected tonsils, teeth, sinuses, or other infections, colds, influenza, pneumonia, overeating, improper diet or over-indulgences; that treatment by the rays would eliminate the condition "auto-toxemia," promote and equalize circulation, relieve congestion in every part of the body, relieve pain and other distressing physical sensations, produce marked relaxation, promote sound and refreshing sleep, remove causes which may lead to surgical operations, stimulate a normal functioning of the various glands and other organs of the body, overcome fatigue, raise the vital tone of the system, thereby increasing both mental and physical efficiency, exert a revitalizing influence upon the sexual or procreative glands, and clear the complexion; that the rays were invaluable as a beauty treatment and would cause absorption of abnormal growths and other deposits such as goiter, tumors of various kinds, and blood clots resulting from hemorrhage due to high blood pressure; that the rays would improve circulation and elimination and thus result in a high state of vitality and a greater resistance to every sort of disease; that the device would treat more than one disease at a time; that the rays would exert a more direct influence upon the large centers of the sympathetic nervous system and the nerve centers of the spinal cord; and that the device and the rays produced were an adequate and competent treatment for asthma, anemia, arthritis, Bright's disease, bladder troubles, bronchitis, colds, constipation, catarrh, catarrhal deafness, diabetes, disorders of the prostate, deafness, eczema, epilepsy, goiter, hay fever, hemorrhoids, heart disease, headache, high blood pressure, indigestion, insomnia, impotence, low blood pressure, lumbago, menstrual troubles, neuralgia, neuritis, nervous irritability, nervous troubles, organic heart disease, obesity, pelvic organ affections, painful menstruation, painful feet, swollen feet, severe pain, paralysis, rheumatism, sciatica, sinus trouble, toxemia, tuberculosis, tumors, ulcers, and varicose veins. The complaint alleged that such representations were false and misleading in that they created the impression that the device when used as directed in the labeling would be of substantial therapeutic value in the treatment of the many and varied human ailments, disorders, and diseases named in the labeling, whereas it was a low-frequency, coreless solenoid which would produce a magnetic field of the same frequency as that of the electric current to which it was attached, and had no therapeutic value.

The complaint alleged further that the defendant would continue to introduce or deliver the device or a similar device for introduction into interstate commerce, misbranded as hereinbefore set forth, or would cause such acts, and would continue to evade and defeat the provisions of the law to the injury of the public unless restrained from so doing, and prayed that the court perpetually enjoin and restrain him and all those acting on his behalf from such unlawful acts; that an order be entered that the defendant show cause why injunction should not issue, and that during the pendency of the action he be enjoined and restrained, and that, upon hearing, a preliminary injunction issue pending the termination of the issues.

On June 29, 1942, the motion for a preliminary injunction having been denied, the case came on for trial on the merits before the court. Evidence was introduced on behalf of the Government and of the defendant, the trial concluding on June 30, 1942. Judgment was entered for the Government on June 30, 1942; the court made the following findings of fact, and conclusions of law:

FINDINGS OF FACT

1.

"I find that the belt with its auxiliary flashlight, is a device within the meaning of Section 331 of Title 21, of the U. S. C. A.

2.

"That this device and the literature which accompanies it is harmless. There is nothing about it that would hurt anyone or harm the citizen. There is about it that which will be helpful to many as examples of the many have been exhibited in this court. Even if one is not afflicted and one thinks one is afflicted and suffers the pain of an affliction which really one does not have, that one is a sufferer nevertheless, and that which remedies the suffering and makes that one well, receives a benefit, so that the device is not only not harmful, but it is beneficial.

3.

"It is misbranded within the meaning of the statute in that it mentions a number of diseases which it manifestly will not cure, nor will it benefit the patient who has them, by the eradication of those diseases, to any extent whatever.

4.

"That it is a coreless solenoid. The larger part of the device is made up of about six hundred coils of electric-carrying wire—that is, a wire which is a conductor. These are tied together, and then covered by a sort of a leather jacket. Running from this device is a cord, electric conductor, which punches into an electric socket, and after that connection with the electric power is made, in order to discover whether electricity is moving from the socket through the device, and perhaps—which the court does not find—to work upon the cupidity of the patient, a smaller circle, or, coil of wire is placed horizontally with the larger coil of wire and then flashes from the inside of the smaller coil a little light like a little electric light globe, showing that the current passes and which did not pass before the cord was placed in the electric socket. That the carrying capacity of this device is approximately forty watts. A smaller amount than is found in the ordinary electric light globe in the ordinary American home.

5.

"That the electricity which passes from the socket to this coiled wire does just that and nothing else, save and except that it raises the temperature of the device somewhat, but not to the extent of increasing circulation, or, increasing gland activity, or, inducing pathology in the body which is enclosed within this circle, as makes the presentment and exposition of this sort of heat to the body, by other devices, effective.

6.

"I think I have said before, but I now find as a fact, that many think that this has benefited, or cured, them of the ailment with which they were suffering, and that they communicated that fact to the defendant and to others."

CONCLUSIONS OF LAW

"From what I have said, it follows as a conclusion of law that the defendant will be enjoined from shipping either the device itself, or, this literature relating to it, or, in any other way, contributing to its sale or distribution in interstate commerce, but not to be interfered with in any way in his continuity, so far as this suit is concerned, in intrastate commerce.

"You will prepare the decree, Mr. District Attorney, to be okayed by the other side, saving such exceptions as they may desire."

On the same date, judgment was entered ordering that the defendant, his agents, employees, representatives, and all others acting by or under his direction or authority, and all persons, firms, or corporations acting with or for him, be perpetually enjoined and restrained from, in any manner or by any

device directly or indirectly, further introducing or delivering for introduction into interstate commerce or causing such act, any device named "Magnetic Ray Appliance," or "Magnetic Ray Instrument," or any similar device similarly labeled in the manner as the said device.

884. Misbranding of Compound Syrup of White Pine and Tar, Medical Compound for Women, and VeDor No. 578 Injection. U. S. v. Primrose R. Devore (Drug Products Co.). Plea of guilty. Fine, $1,500 and 6 months in jail. (F. D. C. No. 7238. Sample Nos. 49046–E, 49048–E, 49049–E.)

On June 29, 1942, the United States attorney for the Southern District of Ohio filed an information against Primrose R. Devore, trading as Drug Products Co., Columbus, Ohio, alleging shipment on or about June 18 and September 4, 1941, from the State of Ohio into the State of Texas of quantities of the above-named products.

Analysis of a sample of Compound Syrup of White Pine and Tar showed that it consisted essentially of small proportions of ammonium chloride, pine tar, menthol and methyl salicylate, sugar, alcohol, and water. The article was alleged to be misbranded (1) in that the name "Compound Syrup of White Pine And Tar Not U. S. P." was false and misleading as it created the impression that the article was "Compound Syrup of White Pine," recognized in the National Formulary, to which tar had been added; and (2) in that the following statements were false and misleading since the article would not be efficacious for these conditions: "A Combination of Meritorious Ingredients Highly Beneficial in Temporary Pulmonary Conditions Caused by Exposure," and "A Successful Preparation for the Treatment of * * * Ordinary Colds, Bronchial Irritations * * * Temporary Relief for * * * Colds * * * Bronchitis, etc."

Analysis of a sample of the Medical Compound for Women showed that it consisted essentially of extracts of plant drugs, including an alkaloid-bearing drug, sugar, and water, preserved with benzoic acid. The article was alleged to be misbranded in that the statement "Medical Compound for Women" was false and misleading as the drug was not efficacious in the cure, mitigation, treatment, or prevention of diseases or ailments of women.

Analysis of a sample of VeDor No. 578 Injection showed that it consisted essentially of small proportions of zinc sulfate, lead acetate, and water. The article was alleged to be misbranded (1) in that the statement "Use in connection with Anti-Gon Internal No. 578" was false and misleading since it implied that this article constituted a part of a treatment for gonorrhea and that when used in connection with another drug, Anti-Gon Internal No. 578, it would be efficacious in the treatment of gonorrhea, whereas the article had no value either alone or in conjunction with such other drug in the treatment of that disease; (2) in that the label failed to declare the common name of each active ingredient since zinc sulfate was not declared; and (3) in that it was a drug in package form and the label failed to bear an adequate statement of the quantity of the contents.

On October 21, 1942, the defendant entered a plea of guilty, whereupon the court imposed a fine of $500 on each of the 3 counts, a total of $1,500, and 6 months in jail on each of the 3 counts, the jail sentences to run concurrently.

885. Misbranding of Glucocinine. U. S. v. Eric M. Boehnke (Glucocinine Company of America). Plea of guilty. Fine, $300 and 4 months in jail. (F. D. C. No. 5581. Sample No. 31575–E.)

On May 13, 1942, the United States attorney for the Eastern District of New York filed an information against Eric Boehnke, trading as Glucocinine Co. of America, at Richmond Hill, N. Y., alleging shipment on or about January 23, 1941, from the State of New York into the State of Michigan of a quantity of Glucocinine which was misbranded.

The article was alleged to be misbranded in that certain statements in the labeling, and a graph purporting to show the reduction of blood sugar brought about by use of the article in experimental animals, were false and misleading in that they represented and suggested that the article would be efficacious in the treatment of light and medium cases of diabetes mellitus, that it would be efficacious as a preventative of diabetes, that it would act beneficially on the pancreas and would arouse the pancreas to new activity, and that it would be efficacious to clear the urine of sugar and reduce the blood sugar to a negative point, whereas it would not be efficacious for such purposes.

It was alleged to be misbranded further in that the statements: "Plant Insulin substances," "Glucocinine * * * is PLANT INSULIN, i. e., substances which occur in large quantities in certain plants and may be regarded as the

origin of insulin," "used daily by thousands of diabetics with best results. It is endorsed by Clinics, sanitariums and physicians," and "free from carbohydrates," appearing in the labeling, were false and misleading since they represented that the article was plant insulin, i. e., an insulin-like substance obtained from plants; that it consisted of substances which might be regarded as the origin of insulin; that it was endorsed in general by clinics, sanitariums, and physicians; and that it was free from carbohydrates, whereas it was not plant insulin; did not consist of substances which might be regarded as the origin of insulin; was not endorsed in general by clinics, sanitariums, and physicians; and was not free from carbohydrates, since it contained starch which is a carbohydrate.

On May 6, 1943, a plea of guilty having been entered, the court imposed a fine of $300 and a sentence of 4 months in jail.

886. Misbranding of Glucocinine. U. S. v. Eric M. Boehnke (Ericus Products Co.). Plea of guilty. Defendant given suspended sentence of 1 year and placed on probation for 2 years. (F. D. C. No. 7252. Sample No. 47691-E.)

On April 3, 1943, the United States attorney for the Eastern District of New York filed an information against Eric M. Boehnke, trading as the Ericus Products Co., at Jamaica, N. Y., alleging shipment on or about December 11, 1941, from the State of New York into the State of Illinois of a quantity of Glucocinine which was misbranded.

Analysis of a sample of the article showed that it consisted essentially of powdered plant tissues, including starch.

It was alleged to be misbranded in that certain statements appearing in the labeling were false and misleading in that they represented and suggested that the articles would be efficacious in the treatment of mild and medium cases of diabetes mellitus, that it would be efficacious to build up the pancreas gland (islets of Langerhans), that it would bring about gradual but lasting alleviation of diabetes; that its use would prevent constitutional breakdown and gangrene in diabetes, that it was more valuable than insulin in the treatment of diabetes, that it would act beneficially on the pancreas and would stimulate the pancreas gland to produce insulin of its own, and that by its use the diabetic could be more liberal in his diet and the tolerance of diabetics for carbohydrates would become greater and greater, whereas it would not be efficacious for such purposes.

It was alleged to be misbranded further in that the statements: "Glycocinine (Vegetable Insulin)," "The medical treatment as a whole in diabetes is for the most part unsatisfactory, unbiological and unscientific," "Honest and conscientious physicians have dropped it for mild and medium cases long ago," "Glucocinine (Plant Insulin) * * * Unlike regular insulin it has the exceptional quality of being able to be administered orally and still retain its full effectiveness. Indeed, it works more slowly than Insulin, but its results are much more permanent and hence more valuable. * * * in short the chief differences between Insulin and Glucocinine are these:—Insulin (important for first aid in severe cases) brings quick results but is habitual and by using it continuously the disease usually progresses. Whereas Glucocinine, on the other hand, works slowly but surely by which the progress of the disease recedes more and more and the tolerance for carbohydrates becomes greater and greater," were false and misleading since the article was not an insulin-like substance obtained from plants; medical treatment in diabetes is not for the most part unsatisfactory, unbiological, or unscientific; honest and conscientious physicians have not dropped insulin for all mild or medium cases of diabetes; the effects resulting from the use of the article were not permanent and were not more valuable than those resulting from the use of insulin; and the article did not differ from insulin only in the respects set forth in the statements aforesaid, but did differ from insulin in the further respect that insulin has the capacity, property, and power of reducing blood sugar, whereas the article Glucocinine did not have such capacity, property, or power.

On May 6, 1943, the defendant having entered a plea of guilty, the court imposed a suspended sentence of 1 year and placed the defendant on probation for 2 years.

887. Misbranding of menstruation tablets, herb tea, and hair pomade. U. S. v. Bernard McBrady (J. E. McBrady & Co.). Pleas of guilty. Sentenced to 1 hour in the custody of the United States marshal. (F. D. C. No. 7287. Sample Nos. 30484-E to 30487-E incl., 47868-E, 47869-E, 47871-E, 47872-E.)

On September 15, 1942, the United States attorney for the Northern District of Illinois filed an information against Bernard McBrady, trading as J. E. McBrady & Co., Chicago, Ill., alleging shipment on or about July 28 and 29 and December 12, 1941, from the State of Illinois into the State of Michigan of quantities of Menstruation Tablets, Herb Tea, and Hair Pomade.

Examination of the Delayed Menstruation Tablets showed the article to contain iron sulfate, extracts of plant drugs, including aloe, and an alkaloid-bearing drug, and oil of savin, coated with calcium carbonate colored red. The article was alleged to be misbranded in that the statements on the label, "Delayed Menstruation," and "For Painful, Suppressed, Profuse or delayed by Colds," were false and misleading as the drug was not efficacious for these purposes.

Examination of the Herb Tea No. 107 showed that the product consisted of senna leaves and pods, uva ursi, chamomile flowers, rosemary leaves, sage leaves, comfrey root, oak bark, orange peel sweet, unicorn root, condurango bark, peppermint leaves, and gentian root. The article was alleged to be misbranded in that the statements appearing on the carton and label represented and suggested that the drug was efficacious in the cure, mitigation, treatment, or prevention of "whites"; that it would save health and prolong life, afford relief from many ills and that it had great healing power, and would maintain life and good health to mankind, were false and misleading as the product was not efficacious for such purposes.

Analysis of Herb Tea No. 110 showed the product consisted essentially of senna pods, malva flowers, horehound, tansy herb, chamomile flowers, comfrey root, cinchona bark, ruta herb, and sage. The article was alleged to be misbranded in that the following statements appearing on the label were false and misleading as the product was not effective for the purposes represented or suggested: "For Delayed Menstruation Caused By Colds * * * Save Your Health Prolong Your Life * * * Relief For Many Ills * * * Great Healing Power * * * to maintain life and good health to man-kind * * * Delayed Menstruation * * * To Aid in bringing back Menstrual Periods delayed by Colds * * * Many Women Suffer more or less every month from delayed menstruation usually caused by colds. This tea is very effective and acts upon the conditions which cause the delays."

Analysis of Herb Tea No. 109 showed the product to consist essentially of senna leaves and pods, cinchona bark, orange peel sweet, comfrey root, clover tops red, sassafras bark, and sarsaparilla root. The article was alleged to be misbranded in that the following statements appearing on the label and in the circular accompanying the drug were false and misleading as the product was not effective for such purposes: "For Skin Eruptions For Minor Skin Eruptions and Pimples, on Face and Body" and "Save Your Health Prolong Your Life * * * For Skin Eruptions For Minor Skin Eruptions and Pimples, on Face and Body * * * The Skin Is An Index To Health Eruptions rarely form upon the surface unless there is something wrong with the system. It is sometimes necessary to treat such eruptions with internal remedies * * * Relief For Many Ills * * * Great Healing Power * * * to maintain life and good health to man-kind."

Examination of Herb Tea No. 114 showed the article to consist essentially of marsh mallow root, coltsfoot leaves, licorice root, mullein leaves, broom tops, and linden flowers. This article was labeled in part: "For Minor Chest Colds." It was alleged to be misbranded in that the statements in the labeling represented and suggested that the drug would be efficacious in the cure, mitigation, treatment, or prevention of minor chest colds, would save health, prolong life, and relieve many ills; that it had great healing power, would maintain life and good health to mankind, be effective for congestion and pain in the chest, would remove and prevent the feeling of oppression and tightness of congestion accompanying the pain in the chest, and irritating cough, were false and misleading as the drug would not be so efficacious.

Analysis of Herb Tea No. 124 showed the product to consist essentially of spearmint leaves, witch-hazel leaves, hops, chamomile flowers, red oak bark, uva ursi leaves, and unidentified plant material. The article was represented by its label "* * * as a wash for Sores, Ulcers," and "* * * also as a wash for Ulcers and other Sores." It was alleged to be misbranded as the drug was not efficacious in the cure, mitigation, treatment, or prevention of sores and ulcers, and it was not efficacious as a wash for sores and ulcers.

Examination of a sample of Herb Tea No. 104 showed the product to consist essentially of senna leaves, chamomile, cascara sagrada, elder flowers, dill seed, caraway, saffron (American), uva ursi, licorice root, peppermint, and sassafras. It was alleged to be misbranded in that the statements in the labeling represented and suggested that the drug was efficacious in the cure, mitigation, treatment or prevention of indigestion, poor appetite, sluggishness, gas, bloating, and biliousness, would save health and prolong life, would clear the accumulated poisonous gas from the colon, relieve a tired and "dopey" feeling, would make

the user feel like a new person, and would prevent toxins and impurities from developing and from being carried to every part of the body, were false and misleading as the article was not so effective.

Analysis of a sample of McBrady's Hair Pomade showed the product to consist essentially of a small proportion of a fatty acid such as stearic acid incorporated in a petrolatum and wax base. The article was alleged to be misbranded in that the statement in the circular accompanying the drug, which represented and suggested that it was efficacious in the cure, mitigation, treatment, or prevention of stubborn and falling hair; that it would give the hair a better chance to grow and cause it to grow faster, and would soften and limber the hair, were false and misleading as the product would not be so effective.

On October 7, 1942, a plea of guilty having been entered, the court imposed upon the defendant a sentence of 1 hour in the custody of the United States marshal.

888. Misbranding of saltpetre. U. S. v. Leon A. Achkinsy (Moore Drug Co.). Plea of nolo contendere. Fine, $150 and 2 years' probation. (F. D. C. No. 7704. Sample No. 83806–E.)

On October 19, 1942, the United States attorney for the Eastern District of Louisiana filed an information against Leon A. Achkinsy, trading as Moore Drug Co., New Orleans, La., alleging shipment on or about September 19, 1941, from the State of Louisiana into the State of Texas of a quantity of saltpetre.

The article was alleged to be misbranded in that the statements on the carton, representing and suggesting that it was "Antiseptic, Diaphoretic, Diuretic, Useful in Gastro-Intestinal Catarrh, Fevers, Asthma, Dropsy, Rheumatism, Etc." were false and misleading since the drug was not an internal antiseptic, a diaphoretic, or diuretic, and it would not be efficacious in the cure, mitigation, treatment, or prevention of the diseases mentioned, or the similar conditions suggested by the abbreviation "Etc."

On October 28, 1942, a plea of nolo contendere having been entered, the court imposed a fine of $150. The imposition of a jail sentence was suspended and the defendant placed on probation for a period of 2 years.

889. Misbranding of Crab Orchard concentrated mineral water. U. S. v. Crab Orchard Mineral Water & Crystal Co., Inc. Plea of guilty. Fine, $100 and costs. (F. D. C. No. 5572. Sample No. 27448–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On or about August 29, 1942, the United States attorney for the Eastern District of Kentucky filed an information against Crab Orchard Mineral Water & Crystal Co., Inc., Crab Orchard, Ky., alleging shipment in the name of L. H. Goodwin & Co. on or about March 23, 1940, from the State of Kentucky to the State of Ohio of a quantity of Crab Orchard concentrated mineral water.

Analysis of a sample of this product showed that it contained dissolved mineral matter, chiefly magnesium and sodium sulfates, with smaller amounts of other salts.

The article was alleged to be misbranded in that statements in the labeling which represented and suggested that it would be efficacious in the treatment and alleviation of conditions for which a sojourn at a mineral spring health resort is customarily prescribed; that it would be efficacious in the relief of inveterate chronic diseases and in the treatment of sickness and suffering; that it would cleanse the system of poisonous toxins and waste matter, and remove the menaces to health resulting from constipation; that it would be efficacious in the treatment of diseases originating from disordered liver and kidneys, and would prevent attacks upon the blood corpuscles by toxins engendered in the system from defective filtration or cleansing; that it would prevent depletion of the nerve cells, and would safeguard beauty in women and keep men fit; that it would be efficacious in the treatment of constipation, rheumatism, headaches, influenza, auto-intoxication, sleeplessness, indigestion, and colds, and that it would keep the blood stream pure, be efficacious for the treatment of skin blemishes and eruptions, make the complexion youthful, clear, and smooth, keep the system internally clean, improve the appetite, and enable one to sleep and feel better, were false and misleading since the article would not be efficacious for such purposes.

On November 9, 1942, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of $100 and costs.

890. Misbranding of Glendage. U. S. v. 46 Packages of Glendage. Consent decree of condemnation. Product ordered destroyed. (F. D. C. No. 5674. Sample No. 27854–E.)

The label of this product bore false and misleading representations that it would be effective in the treatment of the conditions indicated below.

On September 11, 1941, the United States attorney for the Southern District of Indiana filed a libel against 46 packages of Glendage at Indianapolis, Ind., alleging shipment on or about August 1, 1941, by Joseph A. Piuma, from Los Angeles, Calif.

Analysis of a sample of the product showed that each tablet contained glandular material, including ⅛ grain of thyroid, nux vomica extract (containing strychnine), a phosphide such as zinc phosphide, and a laxative drug such as cascara sagrada extract.

The product was alleged to be misbranded in that the following statements were false and misleading since the glandular substances, suprarenal, pituitary, and orchic were not physiologically or therapeutically active when taken by mouth as directed: "Each tablet contains as active ingredients: ⅛ grain desiccated Thyroid, ⅛ grain Extract Nux Vomica, Suprarenal, Pituitary, Orchic substance, Extract Cascara Sagrada and Zinc Phosphide"; "Glendage is recommended as a Tonic for conditions in which may be useful the medicinal benefits of * * * the glandular substances which this preparation is compounded"; "DIRECTIONS Take one Tablet three time a day after meals with a glass of water."

On March 24, 1942, the court for the Southern District of Indiana directed the entry of an order transferring this case for further proceedings to the United States District Court for the District of Arizona.

On December 28, 1942, the court ordered that the request of the claimant for leave to withdraw his answer and entry of judgment as prayed for in the complaint be granted. Pursuant to this order, judgment of condemnation and destruction was entered on December 30, 1942. It was further ordered that a copy of the judgment be sent to the United States marshal for the Southern District of Indiana as a warrant of destruction in accordance with the judgment.

891. Misbranding of Radiol. U. S. v. 6 Cans of Radiol. Default decree of condemnation and destruction. (F. D. C. No. 7079. Sample No. 84320–E.)

On March 21, 1942, the United States attorney for the District of New Jersey filed a libel against 6 cans of Radiol at Bedminster Township, N. J., alleging that the article had been shipped in interstate commerce on or about October 31, 1941, from New York, N. Y., by Middlebrook Lancaster, Inc.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of isopropyl alcohol (64 percent), water, and volatile oil including peppermint oil and eucalyptus oil.

The article was alleged to be misbranded in that certain statements in the labeling which represented that it would be efficacious in the cure, mitigation, treatment, or prevention of atrophy of shoulder muscles, big knee, blemishes (old and recent), bog spavin, bruises, bruised back and withers, capped elbow (shoe boil), capped hock, coughing, curbs, enlarged glands, fistula and quittor, girth galls, grease and mud fever, laryngitis, lymphangitis (big leg), mammitis or garget, over-shot joints (knuckling over), rheumatism, roaring, shoulder and other lameness, shoulder slip, sore back, sore shoulder, sore throat and colds, soreness of back and loins, sprained fetlocks, splints, spavins, ringbones (newly forming), stifle lameness (loose stifle), strain of back, strained tendons (recent), thorough-pin, thick-wind, wheezing, whistling, windgalls (wind puffs), and wounds in animals; and that for human use it would be "marvelously quick in allaying pain in cases of sprains and inflammation," were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further in that its label failed to bear the common or usual name of the active ingredients and a statement of the kind and quantity or proportion of alcohol that it contained.

On July 7, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

892. Misbranding of Sill's Powder Treatment and Sill's Powder Foot Treatment. U. S. v. 21 Packages of Sill's Powder Treatment and 30 Packages of Sill's Powder Foot Treatment. Default decree of condemnation. Product ordered destroyed. (F. D. C. No. 7950. Sample Nos. 73844–E, 73845–E.)

On or about August 28, 1942, the United States attorney for the District of Kansas filed a libel at Topeka, Kans., against 21 packages of Sill's Powder Treat-

ment and 30 packages of Sill's Powder Foot Treatment, alleging that the articles had been shipped on or about February 17 and March 27, 1942, by the Sills Company from Vinita, Okla.

Analysis of a sample showed that the composition of the two products was the same, consisting essentially of salicylic acid, small proportions of bismuth subcarbonate, ammonium alum, boric acid, and aspirin in a base of talc.

The article was alleged to be misbranded in that the statements made in the labeling, which represented and suggested that it was an effective treatment for the relief of feet that itch, scald, crack, blister, burn, ache, swell, and tire quickly, for offensive perspiring feet, painful, calloused feet, and as a general skin remedy; that it would check foot and skin disorders at their start; that it would afford relief for externally caused skin disorders on any part of the body; that it would gradually replace infected, germ-infested, growth-covered, and offensive tissues with a normal epidermis with unobstructed pores which would allow an evenly divided inoffensive perspiration; and that it would be an effective treatment for corns on top of toes, warts, and deeply embedded callouses, trench foot, chillblains, tender spots on feet, ingrown nail discomfort, bunion discomfort, sore corns, itch, water poisonings, poison ivy, impetigo, or 'summer sores,' itching of eczema, scalp irritations, fever blisters, pimples, and irritations, itching piles, checking boils, animal sores, and for mange or similar skin disorders on cats and dogs, were false and misleading since it would not be effective for such purposes.

On October 27, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS FOR VETERINARY USE *

893. Misbranding of GarJEX and Bre-Tone. U. S. v. Near's Food Co., Inc. Plea of guilty. Fine, $150. (F. D. C. No. 7713. Sample Nos. 84365–E, 84366–E, 86226–E.)

On November 10, 1942, the United States attorney for the Northern District of New York filed an information against Near's Food Co., Inc., Binghamton, N. Y., alleging shipment on or about July 25, 1941, and February 18, 1942, from the State of New York into the States of Illinois and New Jersey of quantities of GarJEX and Bre-Tone which were misbranded.

Analyses of samples of the GarJEX showed that it consisted essentially of hexamethylenetetramine, manganese, cobalt, copper, iron, sodium, magnesium and potassium salts including iodides, sulfates and chlorides, together with sulfur and plant material; one sample was found to contain some phosphate and nitrate. It was alleged to be misbranded in that certain statements in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of mastitis or garget, were false and misleading, since the article would not be efficacious for such purposes. It was alleged to be misbranded further in that the name "GarJEX," borne on the label, was misleading since the article was recommended for use as a veterinary drug for administration to cows, and the name suggested and created in the minds of purchasers the impression and belief that it would be efficacious in the cure, mitigation, treatment, or prevention of garget of cows, whereas it would not be efficacious for such purpose.

Analysis of a sample of the Bre-Tone showed that it consisted essentially of salt, epsom salt, calcium diphosphate, cobalt, copper, manganese probably as sulfates, iron probably as oxide, strychnine, potassium iodide and plant material. It was alleged to be misbranded in that certain statements in the labeling which represented and suggested that it would be efficacious as a breeding tonic for cattles, horses, and hogs; that it would be an efficacious treatment for sterility in cattle, horses, and hogs which was not due to diseased conditions of the reproductive organs, were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further in that the name "Bre-Tone" borne on the label and appearing in the circular was misleading since the article was recommended for use as a veterinary drug for administration to horses, cattle, and hogs, and the name suggested and created the impression in the mind of the reader that it would be efficacious as a breeding tonic for horses, cattle, and hogs, whereas it would not be efficacious for such purposes.

On January 26, 1943, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of $150.

*See also Nos. 874, 891, 892.

894. Misbranding of Coxy Check. U. S. v. Clarence A. Near (Near Chemical Co.). Plea of guilty. Fine, $25. (F. D. C. No. 7279. Sample No. 58854–E.)

On July 13, 1942, the United States attorney for the District of Minnesota filed an information against Clarence A. Near, trading as the Near Chemical Co. at Minneapolis, Minn., alleging shipment on or about December 18, 1941, from the State of Minnesota into the State of Iowa of a quantity of Coxy Check which was misbranded.

Analysis showed that the article consisted essentially of calcium carbonate, protein, reducing sugar, citric acid, and cream of tartar.

The article was alleged to be misbranded in that the name "Coxy Check" was false and misleading since it represented, suggested, and implied that the article would be efficacious to check coccidiosis in poultry; whereas it would not be efficacious for such purpose. It was alleged to be misbranded further in that said name and the statement "As a Preventive In a disease as serious as this one, prevention is highly recommended rather than effecting a treatment after the birds have contracted the organism, and the disease. * * * As a treatment. * * * Successful treatment depends on early diagnosis and application. * * * How to Treat:—Mix thoroughly Three level tablespoonsful of Coxy Check in each One-Half Gallon of mash consumed for Seven Days. * * * This preparation is Antiseptic and astringent in nature" were false and misleading since they suggested, implied, and represented that when used as directed, it would be efficacious in the cure, mitigation, treatment, or prevention of coccidiosis in poultry, and that when used as directed it was an antiseptic and astringent; whereas it would not be efficacious for such purposes.

On July 13, 1942, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of $25.

895. Misbranding of Glass Garget Ointment. U. S. v. Howard Glass (Glass Ointment Co.). Plea of guilty. Fine, $100 and costs. (F. D. C. No. 6453. Sample No. 38667–E.)

On September 22, 1942, the United States attorney for the Northern District of Iowa filed an information against Howard Glass, trading as the Glass Ointment Co., Arlington, Iowa, charging shipment on or about March 5, 1941, from the State of Iowa into the State of Minnesota of a quantity of Glass Garget Ointment which was misbranded.

Analysis of a sample of the article showed that it consisted essentially of fatty oils, small proportions of turpentine and creosote incorporated in an ointment base.

The article was alleged to be misbranded in that certain statements in the labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of garget, would relieve hard and congested tissues and local conditions which follow heavy feeding and freshening; that its use in case of udder troubles would restore the udder and teats to normal condition in a short time; that it would relieve caked or inflamed udders, would be efficacious in the cure, mitigation, treatment, or prevention of cow pox, minor cuts, black scab, harness galls, hardening of the quarters, wire cuts, sore hoofs, bunches, collar boils, and swollen throats in cases of distemper and other injuries; that it would remove inflammation from the udders of dairy cows, and would control all kinds of udder trouble in a dairy herd, would be efficacious in the treatment of chicken roup and, when used by man, would be efficacious in the cure, mitigation, treatment or prevention of burns, pimples, boils, and swellings, were false and misleading since the article would not be efficacious for such purposes. The article was alleged to be misbranded further in that it was fabricated from two or more ingredients including, among others, petroleum, kreyslinol (cresol solution), and vegetable oil, and its label failed to bear the common or usual name of each active ingredient.

On September 22, 1942, the defendant having entered a plea of guilty, the court imposed a fine of $100 and costs.

896. Misbranding of Disentone. U. S. v. George D. Solomon and Martin Weinhart (Farm Disentone Company). Plea of guilty. Fines, $25 each and costs. (F. D. C. No. 7675. Sample No. 73037–E.)

On October 20, 1942, the United States attorney for the Northern District of Iowa filed an information against George D. Solomon and Martin Weinhart, trading as Farm Disentone Company, Sioux City, Iowa, alleging shipment on or about December 17, 1941, from the State of Iowa into the State of Nebraska of a quantity of Farm Disentone.

Analysis of a sample of Farm Disentone showed that it consisted essentially of kerosene containing tar and creosote.

The article was alleged to be misbranded in that statements in the label regarding the efficacy of the drug in the cure, mitigation, treatment, or prevention of disease in animals were false and misleading, since the product was not effective for these purposes. The statements represented and suggested: (1) That ailments of poultry and hogs would be practically eliminated ("whipped") by the use of the drug. (2) That the article would be efficacious in preventing germ infection in hogs, cattle, and poultry. (3) That it would be efficacious in the treatment of coughs, colds, and flu in hogs. (4) That it would be efficacious in the treatment of hog scurf, and would cure hog mange. (5) That the use of the drug as directed would enable the user to avoid from 70 to 90 percent of the losses caused by disease in poultry and hogs. And (6), that the drug would be of value in the treatment of ring worms, grub worms, and wire cuts in hogs and cattle.

The article was alleged to be further misbranded in that it was in package form and its label failed to bear any statement of the quantity of contents; and also in that its label failed to bear the common or usual name of each active ingredient.

On October 20, 1942, a plea of guilty having been entered, the court imposed a fine of $25 and half the costs against each defendant.

897. Misbranding of Red-Hed Coxol. U. S. v. Joseph Edward Layton (Production Laboratories). Plea of nolo contendere. Fine, $75. (F. D. C. No. 5512. Sample Nos. 21701–E, 21627–E, 26956–E.)

On March 12, 1942, the United States attorney for the Western District of Washington filed an information against Joseph Edward Layton, trading as Production Laboratories, Seattle, Wash., alleging shipment on or about August 7 and November 5, 1940, from the State of Washington into the State of California of quantities of Red-Hed Coxol which was misbranded.

Analysis of a sample of the article showed that it consisted essentially of an unsaponifiable oil (mineral oil) 60.8 percent, a saponifiable oil consisting in part of fish oil, turpentine 3 percent, a small amount of iodine, and a red coal-tar dye.

The article was alleged to be misbranded in that statements in the labeling which represented and suggested that it would be efficacious as a preventive, treatment, and control for coccidiosis and blackhead in poultry were false and misleading since it would not be efficacious for such purposes.

On October 27, 1942, the defendant having entered a plea of nolo contendere, the court imposed a fine of $75.

898. Misbranding of Mineralized Molactas Block, Turk-A-Tox, Mineral Block, Murco Antiseptic Tablets, and Mineralized Molactas Block – Hog Bricks with Nicotinic Acid. U. S. v. Lapp Laboratories, Inc. Plea of guilty. Fine, $125. (F. D. C. No. 5562. Sample Nos. 16166–E, 39119–E, 39121–E to 39123–E, incl., 39125–E.)

On May 4, 1942, the United States attorney for the Southern District of Iowa filed an information against Lapp Laboratories, Inc., Nevada, Iowa, alleging shipment from on or about April 8 to September 17, 1940, from the State of Iowa into the State of Missouri of quantities of the above-named products that were misbranded.

Analysis of a sample of Mineralized Molactas Block showed that the product consisted essentially of mineral salts, carbohydrates, small proportions of nitrogenous matter, and charcoal. It contained not more than 5.5 percent of crude protein, not more than 37 percent of nitrogen-free extract, 8.6 percent of calcium compounds calculated as calcium, 0.5 percent of phosphorus, and 6.8 percent of salt. Based on this analysis it was alleged that the following statement in a circular accompanying the product was false and misleading: "Nitrogen Free Extract, not less than 63.0% * * * Potassium Iodide * * * Copper Sulphate * * * Calcium * * * 4.2% * * * Iodine * * * .04%, Salt * * * not more than 2.5%." It was alleged to be further misbranded in that the statements appearing on the circular regarding its efficacy in the cure, mitigation, treatment, or prevention of disease in animals were false and misleading, since it would not be efficacious for such purposes. These representations and suggestions were, in part, as follows: For keeping all livestock healthy, for wormy hogs, as a preventive or control of intestinal parasites of hogs, as a preventive of bloating of livestock, as an aid in the control of intestinal worms, as a source of elements healing and soothing to the bruised intestine, and as efficacious in case of necrotic enteritis due to nutritional deficiencies.

Analysis of a sample of Turk-A-Tox showed that it consisted essentially of carbolic acid, gluconic acid, glycerine, and water. The article was alleged to be misbranded in that the statements on the label: "Prophylactic For Turkeys * * * An aid in the control of Blackhead in turkeys," were false and misleading since the article would not be effective for such purposes.

Analysis of a sample of Mineral Block showed that the product consisted essentially of compounds of calcium, and smaller proportions of compounds of sodium, iron, phosphorus, carbonates, chlorides, and sulfates, and contained not more than 26.1 percent of calcium oxide, equivalent to 18.6 percent of calcium and not more than 0.6 percent of phosphorus. Based on this analysis the following statements on the label were alleged to be false and misleading: "Calcium Oxide * * * 30%, Calcium * * * not more than 25%, Phosphorus, * * * not less than 4%, * * * Potassium Iodide, .05%." It was alleged to be further misbranded in that the therapeutic claims made for the article were false and misleading since the article was not effective for such purposes. The representations and suggestions were in part as follows: That the article would improve the appetite and finish of livestock, would increase production of livestock, and the health of livestock; that it would be efficacious in the treatment of various breeding diseases, would stimulate the secretion of the thyroid glands and have a beneficial effect upon the nervous system of the animal, and would have value to the blood.

Analysis of a sample of Murco Antiseptic Tablets showed that the tablets contained calcium, sodium and zinc phenolsulfonates, citric acid, bichloride of mercury 4.2 grains per tablet, and talc. It was alleged to be misbranded: (1) In that statements in the carton and in the label represented and suggested that the article would act as internal antiseptic, prevent or control disease, guard against and reduce the chances of spreading disease, keep the flock healthy, prevent bowel disorders such as indigestion, constipation, pasting up of the vent, and similar troubles; that it would prevent the spread of colds and bronchitis and roupy conditions; that it would be efficacious and beneficial in healing the intestines of the birds after the flock had been wormed; and that the articles would be efficacious in cases of coccidiosis, fowl typhoid, cholera, and worming, were false and misleading since the article would not be efficacious for such purposes. (2) In that its label failed to bear accurate statements of the quantity of the contents in terms of weight and measure. (3) In that its label did not bear a statement of the quantity or proportion of bichloride of mercury which it contained.

Examination of a sample of Mineralized Molactas Block—Hog Brick with Nicotinic Acid, showed that the product consisted essentially of mineral salts, carbohydrates, nitrogenous matter, charcoal, and moisture, and contained not more than 39 percent of nitrogen-free extract, not more than 0.8 percent of phosphorus, not less than 9 percent of calcium, and not less than 7 percent of salt. Based on this examination the following statements, borne on the carton, were alleged to be false and misleading: "Analysis: * * * Nitrogen Free Extract, not less than 63.0%. Potassium Iodide, * * * Calcium * * * 4.2%, Phosphorus * * * 1.4%, Iodine * * * .04%, Salt * * * not more than 2.5%." It was alleged to be misbranded further in that the statements appearing on the circular accompanying the article were false and misleading since they represented and suggested that the article would be efficacious for keeping all livestock healthy; for wormy hogs; for preventing or controling intestinal parasites of hogs; as a preventive of bloating of livestock; in the control of intestinal worms, and as a source of elements that are healing and soothing to the bruised intestines, whereas the article would not be effective for such purposes.

The Mineralized Molactas Block, Mineral Block, and Mineralized Molactas Block with Nicotinic Acid were also misbranded as reported in notices of judgment on foods.

On September 11, 1942, a plea of guilty having been entered to all counts on behalf of the defendant, the court imposed a fine of $25 on each count; the fines on the counts charging violation of the drug sections of the act amounting to $125.

899. Misbranding of Pup-Up Tablets. U. S. v. 2¾ Gross Packages of Pup-Up Tablets. Default decree of condemnation and destruction. (F. D. C. No. 4836. Sample No. 47981–E.)

On June 4, 1941, the United States attorney for the Northern District of Illinois filed a libel against the above-named product at Chicago, Ill., alleging that

the article had been shipped in interstate commerce on or about March 28, 1941, by Arner Co. from Buffalo, N. Y.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of sodium phenobarbital, ephedrine hydrochloride, ephedrine sulfate, starch, and milk sugar.

The article was alleged to be misbranded in that statements in the labeling which represented that it was an effective and appropriate treatment and prophylactic for distemper in dogs were false and misleading since it would not be an effective and appropriate treatment for such condition.

On July 17, 1942, the claimant having withdrawn its claim and answer, judgment of condemnation was entered and the product was ordered destroyed.

900. Misbranding of poultry remedies. U. S. v. 19 Packages of Pratt's Poultry Regulator and 12 Bottles of Pratt's Poultry Inhalant. Default decree of condemnation. Product ordered destroyed. (F. D. C. No. 7413. Sample Nos. 54862–E, 54863–E.)

On April 29, 1942, the United States attorney for the District of New Jersey filed a libel at Trenton, N. J., against 19 packages, each containing 2¾ pounds, of Pratt's Poultry Regulator, and 8 pint bottles and 4 quart bottles of Pratt's Poultry Inhalant, alleging that they were shipped in interstate commerce on or about February 27, 1942, by Pratt Food Co., from Philadelphia, Pa.

Examination of a sample of Pratt's Poultry Regulator showed that it consisted essentially of peanut hull meal, iron oxide, calcium carbonate, bone meal, and Epsom salt, together with small amounts of gentian root, fenugreek and nux vomica, and iodides.

The article was alleged to be misbranded in that the statements appearing in the labeling were false and misleading since they represented and suggested that the article was effective as a regulator, tonic, and appetizer for increasing egg production, was effective for preventing food deficiency diseases, and was effective for building greater vigor and disease resistance in poultry, whereas the article was not so effective.

Examination of a sample of Pratt's Poultry Inhalant showed that it consisted essentially of water, ethyl alcohol, methyl alcohol, formaldehyde, boric acid, and oil of eucalyptus.

The article was alleged to be misbranded in that the statements appearing in the labeling were false and misleading since they represented and suggested that it was effective in the relief, treatment, and prevention of diseases, symptoms, and conditions affecting the respiratory tract of poultry, whereas it was not so effective.

On December 8, 1942, no claimant having appeared, judgment of condemnation was entered and the article was ordered destroyed.

INDEX TO NOTICES OF JUDGMENT D. N. J. NOS. 851–900

PRODUCTS

[1] Injunction issued. Contains findings of fact and conclusions of law.

SHIPPERS AND MANUFACTURERS

[1] Injunction issued. Contains findings of fact and conclusions of law.
[2] Prosecution contested.

[1] Injunction issued. Contains findings of fact and conclusions of law.
[2] Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1944

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

901–950

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

Washington, D. C., August 10, 1944.

CONTENTS [1]

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

901. Action to restrain interstate shipment of "Interferin," a misbranded drug. U. S. v. Don Curtis Keefer (Keefer Laboratories). Permanent injunction granted. (Inj. No. 33.)

On June 29, 1942, the United States attorney for the Northern District of Illinois filed a complaint against Don Curtis Keefer, trading as the Keefer Laboratories at Chicago, Ill., alleging that the defendant for several months past and more particularly on or about November 3 and November 27, 1941, had been and was introducing and delivering for intoduction into interstate commerce, a drug labeled and designated "Interferin"; that the drug was compounded of potassium soap, sodium soap, potassium iodide, benzoic acid, fats and oils, alcohol, and water, and was so compounded and manufactured as to form a paste; that it was sold in a collapsible tube of 60 cc. capacity, bearing a label and packed in a cardboard carton together with implements to be employed in the injection of the paste; that enclosed in the cardboard carton and accompanying the article was a leaflet which contained certain statements in reference to the efficacy of the drug and as to the quantity, dosage, and administration thereof; that the statements appearing in the labeling represented, suggested, and engendered the impression in the mind of the reader that the drug was a safe and effective medicament for effecting abortion, whereas it was not such a safe and effective medicament, but was a drug which has dangerous effects on the human body; and that the article was further misbranded in that it was dangerous to health

[1] For omission of accurate statement of quantity of contents, see Nos. 908, 911, 914, 932, 934; omission of, or unsatisfactory, ingredients statements, Nos. 907, 908, 911, 926, 932, 935, 940, 942; inconspicuousness of required label information, Nos. 913, 923; deceptive packaging, Nos. 930, 938; no new-drug application effective, No. 910; presence of a habit-forming narcotic without warning statement, Nos. 904, 911, cosmetic, subject to the drug provisions of the Act, No. 942.

when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling.

The complaint alleged further that the defendant, unless restrained and enjoined, would continue to introduce and deliver the article for introduction into interstate commerce, misbranded in the manner aforesaid, and would similarly continue to evade and defeat the provisions of the law to the injury of the public; and prayed that the defendant, his agents, employees, and representatives, and all others acting by or under his direction or authority, and all persons, firms, companies, and corporations and their respective officers, servants, employees, and representatives in active concert or participation with the defendant, be perpetually enjoined and restrained from, in any manner of by any device, directly or indirectly, further introducing or delivering the article, or a similar article for introduction into interstate commerce, misbranded in the manner aforesaid, or similarly, and that, upon hearing, a preliminary injunction be granted restraining the defendant during the pendency of the action.

On July 3, 1942, the matter having come on before the court for hearing on the complaint and affidavits filed by the United States attorney, the court entered a preliminary injunction. On July 30, 1942, a permanent injunction was entered as prayed in the complaint.

902. Misbranding of ampuls of sodium salicylate and sodium iodide with colchicine, and adulteration and misbranding of thyroid and ovarian compound. U. S. v. Kenneth Gaylord Ziegler (Ziegler Pharmacal Co.). Plea of guilty. Fine, $450. Payment of fine suspended. (F. D. C. No. 7740. Sample Nos. 40863–E, 42995–E.)

On November 23, 1942, the United States attorney for the Western District of New York filed an information against Kenneth Gaylord Ziegler, trading as Ziegler Pharmacal Company, Buffalo, N. Y., alleging shipment on or about August 19 and September 16, 1941, of the above-named products from the State of New York into the State of Pennsylvania.

Analysis of a sample of the ampuls of sodium salicylate and sodium iodide with colchicine showed that the volume of the contents varied from 18.8 to 20.5 cc. The average was 19.47 cc.

The article was alleged to be misbranded in that the statement, "20 c. c. Plus," borne on the label was false and misleading since it represented that the ampuls contained 20 cc. of the article, plus an amount sufficient to insure a full dosage of 20 cc. when administered in the manner that is customary and usual, whereas a large proportion of the ampuls contained less than 20 cc. of said drug, and all of the ampuls contained less than an amount sufficient to insure a full dosage of 20 cc. when administered in a manner that is customary and usual.

Examination of a sample of the thyroid and ovarian compound showed the tablets to contain 0.015 grain ($\frac{1}{67}$ grain) of arsenic trioxide each.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, $\frac{1}{80}$ grain of arsenic trioxide.

It was alleged to be misbranded (1) in that the statement on the label, "Arsenic Trioxide $\frac{1}{80}$ gr.," was false and misleading since the tablets were found to contain not less than $\frac{1}{67}$ grain of arsenic trioxide; (2) in that its name, "Thyroid and Ovarian (Compound)," was false and misleading since it suggested that the article was composed solely of thyroid and ovarian glandular substances, whereas, in addition, it contained strychnine sulfate and arsenic trioxide; (3) in that the statement, "Ovarian * * * Dose: One or two tablets three times a day," borne on the label was false and misleading since it suggested that in the dosages recommended the drug would supply the user with a significant amount of the active principles of ovarian glands, whereas it contained an inconsequential amount of the active principles of ovarian glands; (4) in that it contained strychnine and, because of the presence of strychnine, not more than the dosage recommended should be taken, its frequent or continued use should be avoided, and its use by children and elderly persons might be especially dangerous; (5) in that it contained arsenic and its labeling did not bear adequate warning that continued or prolonged use of a preparation containing arsenic might result in serious injury; and (6) in that it contained thyroid and would be dangerous to health when used in the dosage or with the frequency of duration prescribed, recommended, or suggested in the labeling.

On November 23, 1942, the defendant entered a plea of guilty to the 3 counts in the information. He was sentenced to pay a fine of $150 on each count, but payment of the fine was suspended.

903. Misbranding of Ju-Van capsules. U. S. v. 292 Boxes of Ju-Van Capsules. Consent decree of condemnation. Product ordered destroyed. (F. D. C. Nos. 1528, 1691, 1847, 1849, 1910. Sample Nos. 90103–D, 4003–E, 4119–E, 4437–E, 4442–E.)

Within the period from on or about February 29 to May 5, 1940, the United States attorneys for the Northern District of Illinois and the Eastern District of Michigan filed libels against the following quantities of Ju-Van capsules: 85 boxes at Chicago, Ill., 142 boxes at Detroit, Mich., 31 boxes at Flint, Mich., and 13 boxes at Lansing, Mich. The libel against the last-named shipment was amended on May 14, 1940, to include an additional 21 boxes of the product. The libels alleged that the article had been shipped in interstate commerce within the period from on or about February 8 to April 20, 1940, by the Mid-West Drug Company, Inc., from Ft. Wayne, Ind.; and charged that it was misbranded.

Examination of samples of the article showed that in 4 of the 5 shipments the capsules contained 1.5 grains of thyroid of United States Pharmacopoeia potency, and plant material, and that in the fifth shipment they contained thyroid equivalent to 1.3 grains of thyroid of the same potency, together with plant material.

The article was alleged to be misbranded in that the statements and designs appearing on the carton labels, "For Overweight Caused by Myxedematous Hypothyroidism (Advanced stage of thyroid deficiency) * * * DIRECTIONS: One capsule after each meal and before retiring, or as directed by physician. In the event distress such as nervousness, insomnia, palpitation, or increased pulse develop, decrease number of capsules taken until condition disappears. If these conditions persist, or if any symptoms of excess thyroid activity appear, or when normal weight is approached, discontinue taking capsules. Advisability of treatment should be determined by physician. WARNING: Not to be used by children nor by persons with Heart Defects, Kidney Diseases, Pregnancy, Diabetes, Goiter, Hyperthyroidism, or any disease or affliction other than overweight as mentioned above," together with further and similar statements contained in the circular shipped with the article, were false and misleading in that they created the impression that the article was a safe and appropriate remedy for overweight, whereas it was not such a safe and appropriate remedy for overweight, but was a dangerous drug, and its labeling failed to reveal the material fact that the use of the article might result in harmful consequences to the user.

It was alleged to be misbranded further in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, "One capsule after each meal and before retiring, or as directed by physician."

On April 29, 1940, no claim having been entered at that time, judgment of condemnation was entered with respect to 69 boxes of the product located at Chicago, and the product was ordered destroyed. However, on May 1, 1940, the Mid-West Drug Co., Inc., having entered an appearance, an order was entered to vacate the default order and the claimant was given further time to answer. On December 3, 1940, on motion of the claimant, the cases instituted in the Eastern District of Michigan were ordered transferred to the Northern District of Illinois for consolidation with the 2 libels filed in the latter District. On June 23, 1943, the claimant having consented to the entry of a decree in the consolidated case, judgment of condemnation was entered and the product was ordered destroyed.

904. Misbranding of Trems. U. S. v. 40 Packages of Trems. Default decree of condemnation and destruction. (F. D. C. No. 10171. Sample No. 32531–F.)

This product consisted of tablets, each containing essentially 1 grain of phenobarbital, 3 grains of aspirin and ½ grain of caffeine.

On July 7, 1943, the United States attorney for the Northern District of Ohio filed a libel against 40 packages of Trems at Cleveland, Ohio, alleging that the article had been shipped in interstate commerce by Trems, Inc., from St. Louis, Mo.; and charging that it was misbranded.

The article was alleged to be misbranded (1) in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, "Dosage: Sleeplessness—For Adults, Two tablets 20 minutes before retiring. Other symptons—One or two tablets as required," since it contained phenobarbital, a drug which cannot be administered with safety except under competent supervision, and the directions which appeared in the labeling did not provide for any limitation in the dosage, but

implied that it might be taken as frequently as desired with safety; (2) in that it was for use by man and contained a chemical derivative of barbituric acid, phenobarbital, which derivative has been found by the Federal Security Administrator, after investigation, to be, and by regulations designated as, habit-forming, and (a) its label failed to bear the statement: "Warning—May be habit forming" in juxtaposition with the name and quantity or proportion of such derivative of barbituric acid, and (b) its label failed to bear, as such regulations specify, the name and quantity or proportion of phenobarbital and the statement: "Warning—May be habit forming," immediately following, without intervening written, printed, or graphic matter, the name by which such drug was titled.

On August 17, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

905. Misbranding of Utra-Jel. U. S. v. 5 Boxes of Utra-Jel. Decree of condemnation and destruction. (F. D. C. No. 6621. Sample No. 54631–E.)

This product, in addition to being dangerous to health when used as directed, bore statements on its labeling which created the false and misleading impression that it was a safe and effective treatment for the conditions indicated below.

On December 29, 1941, the United States attorney for the Eastern District of Pennsylvania filed a libel against 5 boxes, each containing 4 tubes, of Utra-Jel at Philadelphia, Pa., alleging that the article had been shipped on or about November 29, 1941, from Chicago, Ill., by Pynosol Laboratories, Inc.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of a castor oil soap, water, pine oil, and combined iodine.

The article was alleged to be misbranded in that the following statements appearing on its labeling created the false and misleading impression that it was a safe and effective treatment treatment for the conditions hereafter quoted, whereas it was not a safe and effective treatment, but was a dangerous drug: (Tube) "Indicated As An Aid—In Treatment of Minor Infections Of The Cervix And Cervical Canal. As a Uterine Evacuant," (carton) "Indicated as an aid . . . in the treatment of minor infections of the cervix and cervical canal. As a uterine evacuant," (circular) "Cervical Infections And Cervical Erosions (minor) * * * Infections Of The Cervical Canal (Minor) * * * Cystic Cervix * * * As A Uterine Evacuant."

It was alleged to be misbranded further in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof, as follows: (Circular) "take cotton applicator saturated with UTRAJEL and apply to infected parts. If cervix is extensively eroded, apply 1 cc. to 3 cc. on a wool tampon and place against cervix and leave in place about 12 hours. * * * In addition to the same procedure as outlined in the above paragraph, saturate a small gauze packing with UTRAJEL and insert into the cervical canal, leaving a loose end so that the patient may remove in about 12 hours. * * * Prepare field, gently insert sterilized applicator into the external os and pass it careully along the canal and into the mouth of the uterus remembering the position of the uterus as determined by previous bimanual examination. DOSAGE: 5 cc. to 12 cc. the first month, 15 cc. the second month, 20 cc. to 30 cc. the third month and over. The dosages suggested may be varied slightly depending upon the individual case. In all cases treatment should be administered slowly to eliminate as much the possibility of shock * * *."

On November 10, 1942, an answer to the libel having been filed by Pynosol Laboratories, Inc., and later withdrawn, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS[2]

906. Action to enjoin and restrain interstate shipments of a drug designated as Korjena. U. S. v. Jerome V. Gladke (Korjena Medicine Co.). Permanent injunction granted. (Inj. No. 51.)

On March 1, 1943, the United States attorney for the Western District of New York filed a complaint for an injunction against Jerome V. Gladke, trading as the

[2] See also No. 902.

Korjena Medicine Company, Elmira, N. Y., alleging among other things, that, since 1931, the defendant had been engaged in the business of vending throughout the United States a product known as Korjena, and labeled in part as follows: "Korjena A dependable treatment for the reduction of excessive fat . . . Korjena Medicine Co. Laboratories Elmira, N. Y. U. S. A. This treatment is guaranteed dependable and may be taken with complete confidence. Contents 42 Korjena tablets . . . Active ingredients: phenolphthalein, calcium iodide, sodium choleinate"; that the article contained approximately 1 grain of phenolphthalein, approximately .44 grain calcium iodide, calcium carbonate, and bile salts; and that it was misbranded: (a) In that it was recommended as a dependable, safe, and adequate treatment for the reduction of excess fact, which statement was false and misleading since it was not a dependable, safe, and adequate treatment for the reduction of excess fat. (b) In that its label failed to bear adequate directions for use, since the article was a laxative and the directions which appeared on the label provided for continuous administration, whereas a laxative should not be used continuously. (c) In that its label failed to bear such adequate warnings against use in those pathological conditions wherein use of the article might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users since the article was a laxative and its label failed to warn that a laxative should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present. (d) That its label failed to disclose that frequent or continued use of the article might result in dependence upon laxatives. (e) That its label failed to disclose that, if a skin rash appeared, the use of the article should be discontinued.

The complaint alleged further that on or about December 16, 1941, there was filed in the United States District Court for the Western District of New York an information charging a criminal violation of the Federal Food, Drug, and Cosmetic Act against the defendant for shipment of Korjena in interstate commerce to Pittsburgh, Pa., and that on November 10, 1942, the defendant entered a plea of guilty to count 1 of the information and was fined $200; and that while the criminal information was pending as well as afterwards, the following shipments of Korjena were made by the defendant from Elmira, New York: On October 9, 11, and 27, 1942, and on November 25, 1942, shipments were made to Los Angeles, Calif.; on or about November 27, 1942, some 130 packages were shipped to Tampa, Fla.; on or about December 12, 1942, some 63½ dozen packages were shipped to Philadelphia, Pa.; on or about January 2, 1943, some 711 packages were shipped to Kansas City, Mo.; on or about January 2, 1943, some 11¾ dozen packages were shipped to Erie, Pa.; on or about January 9, 1943, some 11 gross packages were shipped to Detroit, Mich.; on or about January 11, 1943, some 9½ dozen boxes were shipped to Minneapolis, Minn.; and on or about February 19, 1943, some 1 dozen boxes were shipped to St. Paul, Minn. It was also alleged that the only difference in composition between the tablets involved in the criminal case and those in the other shipments listed was that the tablets in the criminal case contained the alkaloid strychnine, in addition to the ingredients above set forth.

The complaint alleged further that on April 10, 1938, the Federal Trade Commission directed the defendant and the Korjena Medicine Company to cease and desist from certain unfair methods of competition in connection with the sale of Korjena tablets, which were advertised as a fat-reducing agent and as a remedy for obesity; and that an action was then pending in the United States District Court for the Western District of New York, instituted on or about October 21, 1941, demanding judgment in the sum of $10,000, and further demanding that this defendant be permanently enjoined from violating the terms of the Federal Trade Commission order to cease and desist; and that the defendant, with full knowledge that the labels constituted a violation of the Act, was selling, and had no intention of discontinuing to sell, Korjena under its objectionable label, but on the contrary was then, and so intended in the future, continuing his business, 80 percent of which consisted in the shipping of the product in interstate commerce; and that, unless restrained by the court, the defendant would continue to introduce and offer for introduction and delivery in interstate commerce the misbranded article, and would in this manner continue to violate, evade, and defeat the purposes of the Act, with injury to the public and to the plaintiff.

On March 1, 1943, an order to show cause and a temporary restraining order were filed.

On March 30, 1943, no appearance, responsive affidavit, or pleading having been filed, the court ordered that the defendant, his agents, servants, and employees, and all other persons in active concert or participation with him, be permanently enjoined and restrained from directly or indirectly introducing and delivering for introduction, and causing to be introduced and delivered for introduction, into interstate commerce the article sold under the name Korjena, as then labeled, in violation of the Federal Food, Drug, and Cosmetic Act.

907. Misbranding of Korjena. U. S. v. Jerome V. Gladke (Korjena Medicine Co.). Plea of guilty. Fine, $200. (F. D. C. No. 5517. Sample Nos. 19250–E, 19370–E.)

On December 16, 1941, the United States attorney for the Western District of New York filed an information against Jerome V. Gladke, trading as the Korjena Medicine Co., Elmira, N. Y., alleging shipment on or about September 18, 1940, and January 10, 1941, from the State of New York into the State of Pennsylvania of a quantity of Korjena which was misbranded.

Analysis of a sample of the article showed that it contained phenolphthalein, compounds of calcium and magnesium, iodides, bile salts, and extracts of plant drugs including a strychnine-bearing drug.

The article was alleged to be misbranded in that the statements, "A Dependable Treatment for the Reduction of Excessive Fat * * * This Treatment is Guaranteed Dependable and may be taken with Complete Confidence * * * Especially in overweight cases of long standing these tablets should be faithfully taken regularly as directed. Two or three packages are usually required for the best results * * * This Treatment is dependable in normal conditions * * * All normal cases of excessive weight may confidently follow above directions," borne on the boxes containing the article, were false and misleading since they represented and suggested that the article was a dependable, safe, and adequate treatment for the reduction of excessive fat, whereas it was not a safe, dependable or adequate treatment for such purpose but might produce harmful results. The article was alleged to be misbranded further in that the statement, "Active Ingredients: Phenolphthalein, Calcium Iodide, Sodium Choleinate," borne on the boxes, was false and misleading since the said statement represented and suggested that phenolphthalein, calcium iodide, and sodium choleinate were the only active ingredients, whereas the article contained the active ingredient strychnine in addition to those named; in that it was not designated solely by a name recognized in an official compendium, and was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient, including the quantity or proportion of strychnine contained in it; in that its label failed to bear adequate directions for use since the directions, "Take 1 tablet after each meal * * * Especially in overweight cases of long standing these tablets should be faithfully taken regularly as directed. Two or three packages are usually required for the best results," were not suitable and appropriate directions for the drug, which was essentially a laxative; in that its labeling did not bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since it was a cathartic or laxative and contained phenolphthalein and should not be used when abdominal pain, nausea, vomiting or other symptoms of appendicitis are present, and frequent or continued use might result in dependence on laxatives, and that it should be discontinued if a skin rash should appear

On December 28, 1942, the defendant having entered a plea of guilty, the court imposed a fine of $200.

908. Adulteration and misbranding of Bullock's System Self Treatment for Sinus and Catarrhal Infection. U. S. v. Henry Spangler (National Laboratories, Inc.). Plea of nolo contendere. Sentence of 180 days in jail conditionally suspended. (F. D. C. No. 7209. Sample No. 50930–E.)

This product, which was packed in a cardboard container, consisted of one can of Bullock's Antiseptic Healing and Cleansing Tonic, one jar of Bullock's Nasal Salve, one box of Bullock's Clear Head Tablets, one vial of Sneeze-It, and one bottle each of King Cold Knockout, Ear Oil, Special Sea Salt, and Bullock's Antiseptic Emollient, and a device which included a nasal atomizer of the common variety, an aluminum can with hose connection for irrigating the sinus, a measuring cup, and a thermometer.

On August 19, 1942, the United States attorney for the District of Columbia filed an information against Henry Spangler, trading as National Laboratories, Inc., Washington, D. C., alleging shipment within the period from on or about January 1 to March 1, 1941, from the District of Columbia into the State of Maryland of the above-described products which were misbranded, and portions of which were adulterated.

Analysis of the Antiseptic Healing and Cleansing Tonic showed that it consisted essentially of sodium bicarbonate, sodium chloride, and a small proportion of potassium iodide. Bacteriological examination showed that the article failed to kill *Staphylococcus aureus* at 37° C. and 45° C. in the concentration recommended (1 heaping tablespoonful in 2 quarts of water), or in 10 times that concentration.

The article was alleged to be misbranded in that the statements in the labeling which represented that when used singly or with the device the article was an antiseptic and a healing and cleansing tonic for the nasal cavities; that it was a safe and efficacious treatment of both chronic and acute cases of nasal sinus and catarrhal infection; that it would reduce the inflammation of the membrane and tissue of the nasal cavities; that it would soothe, heal, and refresh the nasal cavities in cases of sinus infection; that it would give strength to the eyes and eyesight; that it would be efficacious in the treatment of hay fever and chronic head colds, and in the treatment of the membrane tissue of the bowel and colon; that it would keep the head cavities clear of mucus and poisonous secretions; that, when weakened as directed, it would be efficacious in the treatment of nasal diseases in persons who have had nasal operations or where the tissues are particularly sensitive; that it would be efficacious in the treatment of the dry form of catarrh and of acid catarrh, and thereby remove the cause of sores in the cavity regions, especially in the nostrils; that it would be invaluable in the treatment of colds and would control the common cold completely; that its use would avoid suffering, save time and obviate costly operations, clear up infection, reduce inflammation, heal irritation, antisepticize the infected part, remove foul pus, mucus, and secretions, and sterilize the infected and diseased parts; that it would automatically cause inflammation of the membrane to subside, and remove obstructions from the mouth of the sinuses and produce a normal drainage; that it would produce immediate relief in cases of acute attacks of sinus and would cure chronic sinus and prevent blindness and deafness by curing sinus diseases; that the article was a complete cure for colds in the head, and would save human life, improve the hearing and promote sleep; that it was a permanent cure for sinus diseases and headaches, would remove from the system poisons caused by sinus infections, and would prevent pneumonia and other serious ills, were false and misleading since it was not an antiseptic and would not accomplish the results claimed.

The article was alleged to be misbranded further in that it was in package form and its label failed to bear an accurate statement of the quantity of contents.

The Antiseptic Healing and Cleansing Tonic was also alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to be an antiseptic, whereas it was not an antiseptic within the meaning of the law in that it was not a germicide when used in the dilutions recommended in the labeling thereof, and did not purport to be, and was not represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

Analysis of the Antiseptic Emollient showed that it consisted essentially of hexylresorcinol, glycerine, and water colored with a green dye. Bacteriological examination showed that the article was not antiseptic and germicidal. It was alleged to be misbranded in that the statements in the labeling which represented that when used singly or with the device it was an antiseptic and germicide and would be efficacious in the cure, mitigation, treatment or prevention of nasal sinus were false and misleading, since it was not an antiseptic or germicide and would not be efficacious for the said purpose.

Analysis of the Nasal Salve showed that it consisted essentially of menthol and camphor incorporated in a base of white petrolatum. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it was efficacious in the cure, mitigation, treatment, or prevention of nasal sinus, and would protect the membrane and tissue from irritation; that it had healing qualities and was efficacious in the treatment of the

dry form of catarrh, stubborn cases of catarrh and acid catarrh that cause sores in a cavity region; and that it was efficacious in clearing the walls of the throat of tight clinging secretion and in clearing blocked eustachian tubes were false and misleading since it would not be efficacious for the purposes represented.

Analysis of the Clear Head Tablets showed that they contained acetanilid 0.90 grain per tablet, sodium salicylate, quinine hydrochloride, and cascara sagrada. They were alleged to be misbranded in that the statements appearing in their labeling which represented and suggested that the tablets were efficacious in the cure, mitigation, treatment or prevention of feverish condition, temperature, headaches, and severe pain resulting from sinus infection, and would provide quick relief in cases of severe sinus pains and headaches were false and misleading since they were not efficacious for such purposes, and would not provide a quick relief in such cases. They were alleged to be misbranded further in that their labeling failed to bear adequate directions for use since the directions upon the label did not provide for any limitation as to the quantity of the tablets to be administered; and in that their label failed to bear adequate warnings against use by children, or in those pathological conditions wherein their use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users since, by reason of the presence of acetanilid in the tablets, frequent or continuous use might be dangerous, causing serious blood disturbances, anemia, collapse, or a dependence on the tablets, and not more than the recommended dosage should be taken, and they should not be given to children.

Analysis of the King Cold Knockout showed that it consisted essentially of sodium bicarbonate, alcohol, and oil of peppermint. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it was efficacious in the cure, mitigation, treatment, or prevention of common colds; that it would dissolve congestion due to common colds by chemical reaction through the chemistry of the body; that it was harmless to the system and would neutralize cold congestion and thereby avoid acute attacks of sinus were false and misleading since it was not harmless to the system and would not be efficacious for such purposes. It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium, and that it was fabricated from two or more ingredients and its label failed to bear a statement of the quantity or proportion of alcohol contained in the article.

Analysis of the Ear Oil showed that it consisted essentially of menthol and camphor in a solution of olive oil. It was alleged to be misbranded (1) in that the statements appearing in the labeling which represented and suggested that it would be a safe and effective treatment for ear trouble resulting from sinus or catarrhal infection were false and misleading since it would not be a safe and effective treatment for such purpose; and (2) in that its label failed to bear an accurate statement of the quantity of the contents of the article.

Analysis of the Special Sea Salt showed that it consisted essentially of approximately 95 percent of sodium chloride and slightly more than 1 percent of potassium iodide. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of sinus and catarrh if used as directed, and would be a valuable assistant in connection with the treatment of chronic sinus and hay-fever were false and misleading since it would not be efficacious or a valuable assistant for the purposes recommended. It was alleged to be misbranded further in that it was in package form and its label failed to bear an accurate statement of the quantity of contents.

Analysis of the Sneeze-It showed that it consisted essentially of camphor and ground-up plant material such as ginger or capsicum. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would create normal functioning of the membrane tissue, would aid to throw off disease, would aid in obtaining speedy results in stubborn and obstinate cases of sinus trouble, and would assist in removing congestion were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further (1) in that it was in package form and its label failed to bear the name and place of business of the manufacturer, packer, or distributor; and (2) its label failed to bear an accurate statement of the quantity of the contents.

The antiseptic Healing and Cleansing Tonic, Antiseptic Emollient, Clear Head Cold Tablets, Ear Oil, Special Sea Salt and Sneeze-It were alleged to be mis-

branded further in that they were not designated solely by names recognized in an official compendium, and each was fabricated from two or more ingredients and the label of each failed to bear the common or usual names of the active ingredients and, in the case of the Clear Head Cold Tablets, failed to bear a statement of the quantity or proportion of acetanilid present.

The device was alleged to be misbranded in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof, particularly the labeling for Bullock's Antiseptic Healing and Cleansing Tonic, and the statements contained in the circular entitled "Directions for use of Bullock's System Home Treatment."

On January 12, 1943, the defendant having changed his original plea of not guilty to a plea of nolo contendere, the court imposed a sentence of 180 days in jail, which was suspended on condition that the defendant was not then selling and would not again engage in the sale of the articles and the device complained of in the information.

909. Misbranding of Dr. Peter's Kuriko. U. S. v. Dr. Peter Fahrney & Sons Co. Plea of nolo contendere. Fine, $250. (F. D. C. No. 6435. Sample No. 60224–E.)

The labeling of this product bore false and misleading therapeutic claims and failed to give adequate directions and warnings for use.

On May 12, 1942, the United States attorney for the Northern District of Illinois filed an information against Dr. Peter Fahrney & Sons Co., a corporation, Chicago, Ill., alleging shipment on or about May 15, 1941, from the State of Illinois into the State of Washington of a quantity of a drug, known as Dr. Peter's Kuriko, which was misbranded.

Analysis showed that this drug consisted of a brown liquid containing chiefly plant extractives, emodin-bearing drugs, sugars, water, and alcohol.

The article was alleged to be misbranded in that the statements regarding its efficacy in the cure, mitigation, treatment, or prevention of disease appearing in the labeling were false and misleading since they represented and suggested that the article was a stomachic and would be efficacious in strengthening the stomach or stimulating its action; that it was a diuretic; that it was efficacious in the cure, mitigation, treatment, or prevention of nervousness, indigestion, and upset stomach, headaches, loss of sleep and appetite, and common colds; that it would produce an excellent effect upon the general state of health and would help the body eliminate waste products by way of the kidneys; that it would aid digestion in the stomach and intestines and thus prepare all foods for use in the body; that it would aid digestion in the intestines by preventing faulty elimination and thus help the entire digestive function, and would remove waste products from the blood and from the tissues of the body; that the drug was efficacious in the cure, mitigation, treatment or prevention of a general feeling of poor health; that it would act on the bowels without griping or purging, and would effectively remove gas and irritating waste matter from the stomach; that it was essential to good health; that it would prevent the many disorders which arise from constipation, such as headache, malaise, nervousness, irritability, and loss of appetite; that it would prevent nervous conditions caused by distress signals arising from the nerve endings in the lower bowel; that it would prevent the serious illnesses resulting from common colds by preventing a run-down condition caused by faulty elimination; that it was efficacious in the cure, mitigation, treatment or prevention of nervousness and weakness following a surgical operation; and that it would improve the appetite, cure nervous indigestion, promote sleep, aid the stomach to function, and regulate the bowels, whereas the article was not a stomachic nor a diuretic, and it was not essential to good health and would not be efficacious, with respect to the other matters as described above.

The article was alleged to be misbranded further in that the label failed to bear adequate directions for its use since the directions did not provide a limitation for the duration of its administration; and in that the label failed (1) to warn that the article should not be taken when suffering from nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and (2) that the frequent or continued use of the article might result in dependence upon a laxative and, by reason thereof, the label did not bear such adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users.

It was alleged to be misbranded further in that certain information required by law to appear in the labeling was not properly placed thereon in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the label contained representations in foreign languages and did not bear in such foreign languages adequate directions or warnings.

On December 1, 1942, the defendant having changed its original plea of not guilty to a plea of nolo contendere, the court imposed a fine of $250 without costs.

910. Adulteration and misbranding of Ridia and misbranding of Sa-Lax. U. S. v. Crawford Foods, Inc., and Harry A. Crawford. Pleas of nolo contendere. Sentences suspended. Defendants placed on probation for 2 years. (F. D. C. No. 7232. Sample Nos. 32621–E, 32622–E, 55392–E, 55743–E.)

On August 3, 1942, the United States attorney for the Southern District of California filed an information against Crawford Foods, Inc., Eagle Rock, Calif., and Harry A. Crawford, alleging shipment within the period from on or about July 26, 1940, to January 12, 1941, from the State of California into the States of Arizona, Washington, and Oregon, of a quantity of Ridia which was misbranded, and a portion of which was also adulterated, and a quantity of Sa-Lax which was misbranded.

Analysis of a sample of Ridia showed that it consisted of tablets containing material derived from plant sources, including alfalfa and a species of mintleaf. Portions of the article were alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since the following statements appearing in a folder entitled, "The Health Chronicle Nature's Printed Guide", issued by the defendant, "I then was able to produce club-root in a tablet form so that each tablet contained a potency equal to two insulin units. * * * Commercially the product will be known as RIDIA and will be distributed exclusively by Crawford Foods, Inc., 2775 Broadway, Eagle Rock, California," purported and represented that each tablet of the article possessed a potency equal to two insulin units, whereas each tablet of the article did not possess a potency equal to two insulin units.

All shipments of the Ridia were alleged to be misbranded in that certain statements in the labeling regarding its efficacy in the cure, mitigation, treatment, or prevention of disease were false and misleading since they represented and suggested that the article, when taken as directed and in accordance with the supplementary needs of the diet, would supply supplementary food for diabetics and would act as a food adjuvant to diets regularly prescribed for persons suffering from diabetes, whereas it would not be efficacious for such purposes.

It was also alleged in the information that the Ridia was a new drug with respect to which no application was effective.

Analysis of a sample of the Sa-Lax showed that it consisted essentially of dried plant materials, including rhubarb root, senna, Irish moss, okra, leafy materials such as parsley, and traces of peanut hulls.

It was alleged to be misbranded in that the statements, "The active principles in this formula are parsley and asparagus. Parsley and asparagus appear to maintain a higher alkalinity through the intestine and into the colon than do other vegetables of higher initial alkaline content," and certain statements regarding the efficacy of the article in the cure, mitigation, treatment, or prevention of disease, borne on the label, were false and misleading in that they represented and suggested that the active ingredients in the article were parsley and asparagus; that parsley and asparagus would maintain a higher alkalinity throughout the intestine and into the colon than do other vegetables of higher initial alkaline content; that it would minimize the alkaline demand upon the liver, that the article would conserve the alkaline demand upon the liver and would facilitate the liver's fabrication and secretion of a more alkaline or normal bile, which would thereby result in more complete digestion, minimized fermentation, and lowered putrefaction within the colon itself, whereas parsley and asparagus were not active ingredients, and parsley and asparagus would not maintain a higher alkalinity through the intestine and into the colon than do other vegetables of higher initial alkaline content, and the article would not be efficacious for the purposes claimed.

The Sa-Lax was alleged to be misbranded further in that its label failed to bear adequate directions for use since the directions appearing on the label, "The dosage of Crawford's Sa-Lax must be determined by the severity of the case. The adult dosage suggested is two tablets upon retiring, to be increased to one tablet four times per day, with meals and upon retiring in the more severe cases. Chil-

dren in proportion to age," suggested continued use of the article, whereas it was a laxative and should not be used continuously.

The Sa-Lax was alleged to be misbranded further in that its label failed to bear such adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since the product contained laxative drugs and therefore should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present; and that frequent or continued use of the article might result in dependence on laxatives.

The Ridia was alleged to be misbranded further under the provisions of the law applicable to foods reported in food notices of judgment.

On November 9, 1942, pleas of nolo contendere having been entered, imposition of sentence was suspended as to both defendants and they were placed on 2 years' probation on each count, to run concurrently.

911. Adulteration and misbranding of salvaged drugs. U. S. v. 50 Cases of Foods and Drugs. Consent decree of condemnation. Products released under bond for segregation and destruction of unfit portion. (F. D. C. No. 7780. Sample Nos. 59789–E to 59800–E, incl., 78301–E, 78302–E.)

These products consisted of approximately 2,500 pounds of fire- and water-damaged and otherwise deteriorated salvaged drug store stock, and included, among other things, baby foods, patent medicines, surgical dressings, and vitamin capsules.

On June 23, 1942, the United States attorney for the Western District of Virginia filed a libel against 50 cases of foods and drugs at Roanoke, Va., alleging that the articles had been shipped in interstate commerce on or about April 16, 1942, from Rutherfordton, N. C., by Dobson and Co.; and charging that the drug items were adulterated and misbranded.

The drug items were alleged to be adulterated in that water and smoke had been mixed therewith so as to reduce their quality.

They were alleged to be misbranded (1) in that the labeling of some of the items contained statements regarding the curative or therapeutic effects of the articles which were false and misleading; (2) in that some of the drugs and merchandise failed to bear labels containing an accurate statement of the quantity of contents of the packages; (3) in that the labels of some of the items did not bear the common or usual name of each active ingredient of the articles; and (4) in that the labeling of some of the items did not bear such adequate warnings against use in those pathological conditions wherein their use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users.

On September 2, 1942, Dobson and Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the food and drugs which had been seized were ordered released under bond for segregation and destruction of the unfit portion under the supervision of the Food and Drug Administration.

912. Misbranding of Analgesic Balm. U. S. v. 11¾ Dozen Packages of Analgesic Balm. Default decree of condemnation. Product ordered delivered to a charitable institution. (F. D. C. No. 6728. Sample No. 74177–E.)

On January 19, 1942, the United States attorney for the District of New Jersey filed a libel against 11¾ dozen packages of Analgesic Balm at Irvington, N. J., alleging that the article had been shipped in interstate commerce on or about August 23 and November 10, 1941, by the Harris Chemical Corporation from New York, N. Y.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of volatile oils such as methyl salicylate, camphor, and menthol, incorporated in a base composed of a mixture of petroleum derivatives, and lanolin.

The article was alleged to be misbranded in that its labeling failed to bear adequate directions for use, i. e., the labeling bore no directions for use.

It was alleged to be misbranded further in that the following statements in the labeling: (Display carton) "Relieves Cold and Rheumatic Pains, Neuralgia, Simple Colds," (retail carton) "For the Relief of * * * Bronchial Irritation," and (tube label) "For the Relief of Rheumatism, Neuralgia, Gout, Headache, etc.," were false and misleading since the product was merely a counter-irritant and would not be capable of producing the effects implied or claimed in the labeling.

On July 14, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a charitable institution after its labeling had been destroyed.

913. Misbranding of Ocean-Lax. U. S. v. 29 Bottles of Ocean-Lax. Decree of condemnation and destruction. (F. D. C. No. 6368. Sample Nos. 40885–E, 40886–E.)

On December 6, 1941, the United States attorney for the Eastern District of Pennsylvania filed a libel against 29 bottles of Ocean-Lax at Philadelphia, Pa., alleging that the article had been shipped in interstate commerce within the period from on or about July 3 to August 11, 1941, by the Mineralized Foods, Inc., from Baltimore, Md.; and charging that it was misbranded.

Analysis of the article showed that it consisted essentially of senna pods, purging cassia, rhubarb root, sea weed, and mint leaves. It contained a total mineral matter of 0.18 grain per tablet and total iodine of 0.4 milligram per tablet.

The article was alleged to be misbranded (1) in that its labeling failed to bear adequate directions for use since the directions on the label, "If necessary 1 to 2 Ocean-Lax Tablets before or after each meal and before retiring, with water or fruit juice, preferably unsweetened grapefruit juice, at least ½ glassful. Increase or decrease intake to meet individual requirements. For children over 4 years reduce intake to ½ or less," did not constitute appropriate directions for use of this laxative drug, since they provided for frequent and continued use which might result in injury to the consumer by establishing dependence upon laxatives to move the bowels; (2) in that the statement "Each Ocean-Lax Tablet averages approximately 1½ milligrams of natural organic food iodine," borne on the label, was false and misleading since each tablet contained only 0.4 milligram of iodine; (3) in that the designation "Ocean Lax," borne on the label, was false and misleading since the laxative ingredients in the article, senna pods, purging cassia, and rhubarb root, are not obtained from the ocean; (4) in that the statements on the label, "More Than A Laxative. Mineralized With Imported Sea Plants. Consists of an imported rare variety of Sea Vegetables, high in alkalinity and food minerals carefully blended with Senna Fruit, Peppermint Leaves, ripe fruits of Cassia Fistula and Chinese Rhubarb, U. S. P.," were false and misleading because the alkalinity of the article and the amount of minerals supplied by it were inconsequential, and because the label failed to reveal the material fact that sea plants and peppermint leaves do not contribute in a material respect to the effects of the article; and (5) in that the common or usual name of each active ingredient, required by law to appear upon the label, did not appear prominently placed thereon and in such terms as to render it likely to be understood by the ordinary individual under customary conditions of purchase and use, since the label did not show that the only active ingredients in the preparation were senna pods, purging cassia, and rhubarb root.

The libel alleged that the article was also adulterated and misbranded under the provisions of the law applicable to foods, reported in food notices of judgment.

On March 4, 1942, the Mineralized Foods, Inc., claimant, having filed an answer denying the adulteration and misbranding charges in the libel, and having filed a motion for removal of the proceedings to the District of Maryland in which District the claimant had its principal place of business, the court denied such motion, handing down the following opinion:

MOORE, *District Judge:* "This is a suit by the United States of America under the Federal Food, Drug & Cosmetic Act of June 25th, 1938, to condemn twenty-nine bottles more or less of a product called "Ocean-Lax." The libel charges adulteration and misbranding. The articles were seized in the city of Philadelphia, in the Eastern District of Pennsylvania, in the hands of Thomas Martindale and Company, and are still in this District.

"Motion has been filed by Mineralized Foods, Inc., claimant of the products seized, for an order to remove the case for trial to the District Court of the United States for the District of Maryland. The ground for the motion is that the claimant, Mineralized Foods, Inc., is a corporation having its principal place of business in the city of Baltimore, Maryland. The claimant relies upon the provisions of the act set out in Section 394 (a) (21 U. S. C. A. sec. 334) of which the pertinent portion is as follows: 'In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in

case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States Attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.'

"It is contended by the claimant that because its place of business is located in the District of Maryland and because the act provides that unless good cause to the contrary is shown by the Government it is entitled to have the Court specify a Court of 'reasonable proximity' to its principal place of business as the place of trial, it therefore necessarily follows that a removal order should be entered, and that the District Court for the District of Maryland is the proper place to which the case should be removed. The Government contends on the other hand that a proper interpretation of the Act, particularly in view of its legislative history, does not permit the Court to remove the case to the district of claimant's residence; in other words that the term 'reasonable proximity' must be held to exclude the claimant's own district.

"I do not find it necessary to decide this point in passing upon the motion. The parties having failed to stipulate with reference to any district to which the case should be removed, the Court's duty is to specify a district of 'reasonable proximity' *unless good cause to the contrary is shown.* I am of the opinion that whenever it appears that the seizure has been made and the libel filed in a district which is itself of 'reasonable proximity' to the claimant's principal place of business, that fact alone constitutes good cause against removal. The Eastern District of Pennsylvania is a district of 'reasonable proximity' to the claimant's principal place of business. The District Court for that district sits in the city of Philadelphia which is approximately one hundred miles distant from claimant's principal place of business. It is imposing no hardship upon the claimant in this instance to require the case to be tried in the district where the libel is filed. It appears that the seized products are situated in this district and were in the hands of a person other than the claimant when seized; and it is further stated by the Government that many of the witnesses are in this district.

"Claimant's motion will be denied. An order may be prepared and entered in accordance with this opinion."

On January 7, 1943, the claimant having withdrawn its claim and answer, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

914. Adulteration and misbranding of milk of magnesia, chloroform liniment, ammonia water, and saturated solution of boric acid. U. S. v. Frank C. Garlett (Lee Drug Sales Co.). Plea of nolo contendere. Fine, $250. (F. D. C. No. 6458. Sample Nos. 65058–E, 65126–E, 65127–E, 65129–E, 65170–E.)

These products were sold under names recognized in the United States Pharmacopoeia or National Formulary, official compendiums, and differed in strength and quality from the standard prescribed therein. The boric acid was also contaminated, one lot with an oily substance and the other lot with mold.

On August 4, 1942, the United States attorney for the District of Colorado filed an information against Frank C. Garlett, trading as the Lee Drug Sales Co., Denver, Colo., alleging shipments on or about March 28, April 28, and June 3, 1941, from the State of Colorado into the States of New Mexico and Wyoming of quantities of the above-named drugs which were adulterated and misbranded. The drugs were labeled in part: (Bottles) "Garlett's Milk of Magnesia * * * Distributed by D. W. Garlett Drug Stores Cheyenne, Wyoming," "Lee's Saturated Solution of Boric Acid," "Hytest * * * Chloroform Liniment," or "Hytest * * * Ammonia Water"; (tags attached to bottles of liniment and ammonia) "Distributed By Hytest Drug Co. Denver, Colo."

The milk of magnesia was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, but its strength differed from and its quality fell below the standard set forth therein since it contained not more than 6.11 percent of magnesium hydroxide, whereas the Pharmacopoeia provides that milk of

magnesia shall contain not less than 7 percent of magnesium hydroxide; and its difference in strength and quality from the official standard was not plainly stated on the label. It was alleged to be misbranded in that the statement "Milk of Magnesia U. S. P.," appearing in its labeling, was false and misleading.

The chloroform liniment was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, but its strength differed from and its quality fell below the standard set forth therein since it contained not more than 38.1 percent of alcohol by volume, whereas the Pharmacopoeia provides that it shall contain from 43 to 47 percent of alcohol by volume; and its difference in strength and quality from the official standard was not plainly stated on the label. It was alleged to be misbranded in that the statement "Chloroform Liniment * * * Alcohol 45% to 47%," appearing in its labeling, was false and misleading. It was alleged to be misbranded further in that it was in package form and did not bear a label containing an accurate statement of the quantity of contents since the bottle label bore the statement "One Pint," whereas the bottle contained not more than 14.6 fluid ounces of the drug.

The ammonia water was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, but its strength differed from and its quality fell below the standard set forth therein since it contained not more than 7.54 grams of ammonia per 100 cc., whereas the Pharmacopoeia provides that ammonia water shall contain not less than 9 grams of ammonia per 100 cc.; and its difference in strength and quality from the official standard was not plainly stated on the label. It was alleged to be misbranded in that the statement "Ammonia Water U. S. P.," appearing in its labeling, was false and misleading; and in that it was in package form and its label failed to bear the name and place of business of the manufacturer, packer, or distributor of such drug.

The saturated solution of boric acid was alleged to be adulterated in that it consisted in whole or in part of a filthy substance; and in that it purported to be and was represented as a drug, the name of which is recognized in the National Formulary, but its strength differed from and its quality fell below the standard set forth therein since one shipment of the drug contained not more than 3.1 grams of boric acid per 100 cc. and the other shipment contained not more than 3.75 grams per 100 cc., whereas the Formulary provides that solution of boric acid, which is a synonym for saturated solution of boric acid, shall contain not less than 4.25 grams of boric acid per 100 cc., and its difference in strength and quality from such standard was not plainly stated on the label. This drug was also alleged to be misbranded in that the statements appearing on its label "Saturated Solution of Boric Acid," and "As an eye wash, use full strength in an eye cup as often as necessary," were false and misleading since they represented that the drug was a saturated solution of boric acid and that the drug would be suitable for use as an eye wash, whereas it was not a saturated solution of boric acid and it would not be suitable for use as an eye wash by reason of the fact that one shipment of the drug was contaminated with an oily substance and the other shipment was contaminated with a moldy substance.

On February 25, 1943, the defendant having entered a plea of nolo contendere, the court imposed a fine of $25 on each of the 10 counts, totaling $250.

915. Adulteration of Athlete's Isopropyl Alcohol Compound. U. S. v. The Spark'l Paulette Co., Inc. Plea of guilty. Fine, $1,000. (F. D. C. No. 7677. Sample No. 77201–E.)

On April 3, 1943, the United States attorney for the Eastern District of New York filed an information against the Spark'l Paulette Co., Inc., Brooklyn, N. Y., alleging shipment on or about April 20, 1942, from the State of New York into the State of Pennsylvania of a quantity of Athlete's Isopropyl Alcohol Compound which was adulterated.

The article was alleged to be adulterated in that it consisted in whole or in part of a filthy substance by reason of the presence therein of rodent hairs, human hairs, insect larvae, metal fragments, rust, and miscellaneous dirt. It was alleged to be adulterated further in that it had been prepared and packed under insanitary conditions whereby it might have become contaminated with filth.

On April 22, 1943, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of $1,000.

916. Adulteration of Isopropyl Alcohol Compound. U. S. v. 40 Dozen and 80 Dozen Bottles of Isopropyl Alcohol Compound. Decrees of condemnation. Product ordered sold to be used for industrial purposes. (F. D. C. Nos. 7471, 7498. Sample Nos. 77124–E, 77201–E.)

Examination showed that this product was contaminated with filth in the form of rodent hairs, human hairs, insect larvae, metal fragments, dust, and miscellaneous dirt. Inspection of the factory premises revealed the existence of very filthy conditions.

On May 6 and 13, 1942, the United States attorney for the Eastern District of Pennsylvania filed libels against 120 dozen bottles of Isopropyl Alcohol Compound at Philadelphia, Pa., alleging that the article had been shipped on or about March 5 and April 20, 1942, from Brooklyn, N. Y., by the Spark'l Co.; and charging that it was adulterated in that it was contaminated with filth, and in that it had been prepared and packed under insanitary conditions whereby it might have become contaminated with filth. The article was labeled in part: "Athlete's Isopropyl Alcohol Compound."

On April 2, 1943, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed. On June 7, 1943, amended decrees were entered ordering the product to be sold on condition that it be used only for industrial purposes.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS[3]

917. Adulteration and misbranding of digitalis tablets, misbranding of cascara compound tablets, alleged adulteration of cascara compound tablets, and alleged adulteration and misbranding of posterior pituitary solution. U. S. v. Buffalo Pharmacal Co., Inc., and Joseph H. Dotterweich. Counts charging adulteration of cascara compound tablets and adulteration and misbranding of posterior pituitary solution nolle prossed. Pleas of not guilty. Tried to the court and jury. Verdict of guilty as to the individual defendant; disagreement as to the corporate defendant. Fine, $500 on each of 3 counts against individual defendant; payment of fines on counts 2 and 3 suspended and the individual defendant placed on probation. Judgment reversed on appeal to the Circuit Court of Appeals. Petition for Writ of Certiorari granted and decision rendered by Supreme Court reversing the judgment of the Circuit Court of Appeals. (F. D. C. Nos. 951, 2087. Sample Nos. 78710–D, 78786–D, 78814–D.)

On April 29 and August 5, 1940, the United States attorney for the Western District of New York filed informations against the Buffalo Pharmacal Co., Inc., and Joseph H. Dotterweich, secretary and general manager of the corporation, alleging shipment on or about October 2, 1939, and January 8, 1940, from the State of New York into the States of Pennsylvania and Ohio of a quantity of digitalis tablets which were adulterated and misbranded, a quantity of cascara compound tablets which were misbranded and were alleged to be adulterated, and a quantity of posterior pituitary solution which was alleged to be adulterated and misbranded.

The digitalis tablets were alleged to be adulterated in that their strength differed from and their purity or quality fell below that which they purported or were represented to possess since each tablet was represented to possess a potency of one U. S. P. digitalis unit, whereas each tablet possessed a potency of not more than 0.48 U. S. P. digitalis unit per tablet. They were alleged to be misbranded in that the statement, "Tablets Digitalis 1½ Grs * * * One USP Unit Represents (0.1 gram equals 1.543 grains) Powdered Digitalis," borne on the label attached to the bottle containing the article, were false and misleading in that the statements represented that each tablet possessed a potency of 1 U. S. P. digitalis unit, whereas each tablet did not possess such potency.

The cascara compound tablets were alleged to be misbranded in that the statement, "Tablets Cascara Compound * * * (Hinkle)," borne on the bottle label, was false and misleading since it purported and represented that the article consisted of tablets of compound cascara (Hinkle), a drug the name of which, i. e., "Compound Pills of Cascara" and "Hinkle's Pills" is recognized in the National Formulary, whereas it did not consist of tablets of compound cascara (Hinkle) since it contained strychnine sulfate, an ingredient which is not included in the formula set forth as the standard for compound pills of cascara (Hinkle's Pills) in the National Formulary, official at the time of the investiga-

[3] See also Nos. 902, 908, 910, 914.

tion of the article. The Tablets Cascara Compound were also alleged to be adulterated on the ground that their strength and quality differed from the standard set forth in the National Formulary for Compressed Pills of Cascara, and Hinkle's Pills.

Adulteration and misbranding was also charged against a shipment of "Posterior Pituitary Solution" on the ground that its potency exceeded by 50 percent the potency of the product recognized under that name in the National Formulary.

On March 11, 1941, the defendants were arraigned and pleas of not guilty were entered on their behalf. On March 15, 1941, the defendants filed motions to quash the informations on the grounds (1) that, with respect to the digitalis tablets and posterior pituitary solution, alleged guaranties that the products complied with the law had been received by the defendant company from the vendors, and that the products had been repacked and sold without change in strength and quality; (2) with respect to the cascara compound tablets that they were labeled "Tablets Cascara Compound No. 2 S. C. Pink, (Hinkle)," and were a different product than that recognized in the National Formulary under the name of "Compound Pills of Cascara" and "Hinkle's Pills" and that there is a distinction between pills and tablets; and (3) that the individual defendant was in no way involved in any alleged adulteration and misbranding as charged since his name did not appear in the labeling of the products.

On May 8, 1941, after arguments of counsel, the motions to quash were denied by the court on the basis that objections to the informations were matters of defense which should be brought up at the trial. Subsequently, on motion of the United States attorney, the counts charging adulteration of the cascara compound tablets and adulteration and misbranding of the posterior pituitary solution were nolle prossed. The two informations were consolidated for trial before a jury on June 30, 1941, on which date the trial commenced. The taking of testimony was concluded on July 2, 1941, the jury was charged and retired and, after deliberation, returned, on the same day, a verdict of guilty on all counts as to the individual defendant, and reported a disagreement as to the corporate defendant. The individual defendant appeared for sentence on September 8, 1941, and at that time presented an argument in support of a motion to set aside the verdict. Sentence was thereupon deferred for the purpose of considering the merits of the motion and on October 17, 1941, the following opinion in denial of the motion was handed down by Hon. Harold P. Burke, United States District Judge:

BURKE, *District Judge:* "The defendant, Joseph H. Dotterweich, moves to set aside the verdict of the jury upon the ground that it was against the law and against the weight of the evidence, that the verdict as to the defendant Dotterweich was inconsistent with the disagreement of the jury in regard to the corporate defendant and therefore an illegal verdict, and that the failure of the Government to prove notice to the defendant Dotterweich of an intended prosecution under the Food, Drug and Cosmetic Act, June 25, 1938, c. 675, 52 Stat. 1040 was a condition precedent to the commencement of a proceeding against him, without which there could be no valid proceeding.

"There was sufficient evidence upon which the jury could base a verdict of guilty. The verdict was not inconsistent with the jury's treatment of the corporate defendant as to which it reached no verdict. Notice pursuant to Section 335, Title 21, U. S. C. A. of a contemplated criminal proceeding was given to the corporate defendant. Dotterweich was the General Manager and had actual notice of the contemplated proceeding against the corporation. There is nothing in the statute limiting prosecutions to those cases that have been reported by the Secretary to the United States Attorney. Prosecution for violation of the statute arising independently of any report by the Secretary would require no preliminary notice. The absence of such a limitation indicates that the requirement for notice under Section 335 should be construed as an administrative provision imposing a duty upon the Secretary. The reasoning adopted by the Supreme Court in United States vs. Morgan, 222 U. S. 274, in construing a provision for preliminary notice under the former statute, Section 4, Pure Food and Drug Act of June 30, 1906, 34 Stat. L. 768 C. 3915, applies with equal force to the notice required under the present statute. It was there held that the requirement for notice was not jurisdictional. I think the same reasoning impels a like conclusion here.

"Motion denied."

On October 27, 1941, the individual defendant was sentenced to pay a fine of $500 on count 1 of the consolidated information. Fines of $500 were also imposed on such defendant with respect to the other 2 counts of the information, but payment thereof was suspended and the defendant was placed on probation for 60 days. The case was thereafter appealed to the United States Circuit Court of Appeals for the Second Circuit, and on December 3, 1942, the following decision was handed down reversing the judgment of the District Court:

SWAN, *Circut Judge:* "The appellant was prosecuted, together with Buffalo Pharmacal Company, Inc., a New York corporation of which he was general manager, for violations of section 301 (a) of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. S331 (a). Three counts of the informations were submitted to the jury. The first count was based on an interstate shipment on October 2, 1939 of a bottle of cascara compound which was charged to be misbranded, 21 U. S. C. A. S352 (a); the other two counts related to an interstate shipment on January 9, 1940 of a bottle of digitalis tablets, one of the counts charging adulteration, 21 U. S. C. A. 351 (c), and the other misbranding, 21 U. S. C. A. S352 (a). Each of the shipments was made in filling an order received through the mails by Buffalo Pharmacal Company from a physician resident in a state other than New York. The corporation had purchased the drugs from a wholesale manufacturer; it repackaged them for the shipments under attack. The appellant Dotterweich had no personal connection with either shipment, but he was in general charge of the corporation's business and had given general instructions to its employees to fill orders received from physicians. The jury found guilty on all three counts. For some unexplainable reason it disagreed as to the corporation's guilt. The sentence imposed on the appellant was a fine of $500 on each count, with payment suspended on the second and third counts, and probation for 60 days on each count to run concurrently.

"The bottle of cascara compound carried a label reading '1000 Tablets Cascara Compound * * * (Hinkle),' followed by a list of the ingredients, one of which was strychnine sulphate. The charge of misbranding was based on the fact that this ingredient had been removed from the formula for Hinkle pills stated in the official National Formulary [4] promulgated January 1, 1939. The issue left to the jury was whether the label was false and misleading in that it would lead the purchaser or the general public to believe that the tablets contained only the ingredients designated in the official formula for Hinkle pills. Since intention to violate the statute is immaterial in a charge of misbranding,[5] we think the jury's finding that the label was false and misleading was not unsupported by the evidence.

"The label on the bottle of digitalis tablets represented that each tablet possessed a potency of one U. S. P. unit of digitalis, whereas in fact analysis proved that the tablets were less than one-half of the represented potency. This was so far below the standard that findings of adulteration and misbranding would seem to be inevitable, unless the deterioration occurred after the bottle of tablets was shipped. It was shipped on January 9, 1940 and its contents were analyzed by government chemists in March 1940. While cross examination brought out that digitalis tablets may deteriorate in potency by lapse of time if not properly stored, there was some testimony to indicate that the bottle in question had been properly cared for. We cannot say that the evidence was insufficient to support the verdict of adulteration and misbranding."

"Section 305 of the Act, set forth in the margin,[6] provides that before the Administrator reports a violation to any United States attorney for prosecution, 'the person against whom such proceeding is contemplated' shall be given notice and a hearing. In the case at bar such notice was addressed only to the corporation. In response thereto the appellant appeared on behalf of the corpora-

[4] See 21 U. S. C. A. S321 (j) and (n).

[5] See Von Bremen v. United States, 192 F. 904, 906 (C. C. A. 2), Weeks v. United States, 224 F. 64, 68 (C. C. A. 2), and Strong, Cobb & Co. v. United States, 103 F. 2d 671, 674 (C. C. A. 6) construing the Food and Drugs Act of 1906. That intention is not necessarily an element of the offense under the existing Act is made very clear by section 303, 21 U. S. C. A. S333 (a) and (b) where different penalties are provided for simple violations and for violations "with intent to defraud or mislead."

[6] 21 U. S. C. A. S335. Hearing before report of criminal violation. Before any violation of this chapter is reported by the Administrator to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

tion. He contends that a notice addressed to him personally was a condition precedent to his lawful prosecution. The district judge ruled that the provision for notice and a hearing was an administrative direction to the Administrator rather than a jurisdictional requirement for criminal proceedings. We agree with this conclusion. Such was the authoritative construction placed upon a similar provision in the Food and Drugs Act of 1906, 21 U. S. C. A. S11. *United States* v. *Morgan*, 222 U. S. 274; see also *United States* v. *King & Howe*, 78 F. 2d 693, 696 (C. C. A. 2). In our opinion the changes in phraseology introduced by the 1938 Act are not such as to render obsolete these decisions. This appears quite clearly from the Congressional debates. 83 Cong. Rec. pp. 7792, 7794, 75th Cong., 3d sess. Articles by certain commentators are cited as expressing the opposite view,[7] but we are constrained to disagree with them.

"The appellant further urges that the jury's failure to convict the corporation is so inconsistent with the finding of guilt on the part of the appellant that the verdict against him cannot stand. Assuming that the statute includes within its prohibitions an agent who acts for his employer in shipping in interstate commerce misbranded or adulterated articles, the contention is without merit. No authority has been cited in support of the argument that failure to convict the principal will avoid the conviction of an agent who has committed all the elements of a crime. We think the usual principle is applicable that error cannot be asserted for inconsistency in the jury's verdict. See *Dunn* v. *United States*, 284 U. S. 390; *United States* v. *Pandolfi*, 110 F. 2d 736 (C. C. A. 2).

"A more difficult question is presented by the appellant's contention that the statute is aimed only at punishment of the principal and not at punishment of an innocent agent who in good faith and in ignorance of the misbranding or adulteration takes part in an interstate shipment of food or drugs. Section 301, 21 U. S. C. A. S331, prohibits 'the following acts and the causing thereof,' namely '(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.' Section 333 (a) of Title 21 declares that 'any person' who violates any of the provisions of section 331 shall be guilty of a misdemeanor and on conviction be subject to imprisonment or fine or both. The Act defines the term 'person' to include 'individual, partnership, corporation and association.'' 21 U. S. C. A. S321 (e). Who is the person causing 'the introduction or delivery for introduction' into interstate commerce of a misbranded drug? Is the clerk who innocently packs or ships it guilty of the offense, as well as the employer for whom he works? While the statutory language seems literally to include all who have any part in causing delivery for introduction into interstate commerce, there are serious objections to so construing it. Subsection (c) of 21 U. S. C. A. S333 provides 'No person shall be subject to the penalties of subsection (a) of this section * * * for having violated section 331 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in the case of an alleged violation of section 331 (a), that such article is not adulterated or misbranded within the meaning of this chapter designating this chapter * * *' Obviously such a guaranty, if given, will be obtained by the drug dealer, not by his clerk who may later deliver the article for shipment in interstate commerce; nor is such clerk literally within the protection of the quoted section, since he is not the one who 'received' the article from the guarantor. It is difficult to believe that Congress expected anyone except the principal to get such a guaranty, or to make the guilt of an agent depend upon whether his employer had gotten one. The agent's guilt, like his principal's, must be independent of any scienter under section 331 (a). It would be extremely harsh to charge him criminally with the risks of the business as the drug dealer is himself charged. A majority of the court is of opinion that this cannot have been the congressional intent and that the statute must be construed to mean that only the drug dealer, whether corporation or individual, is the 'person' who causes the 'introduction' or 'delivery for introduction' of misbranded or adulterated drugs into commerce. In support of this conclusion the appellant adverts to the omission from the present Act of a provision which appeared in the 1906 Act in 21 U. S. C. A. S4. This declared that in construing and enforcing the provisions of sections 1 to 15 of Title 21 "the act, omission, or failure of any officer, agent or other person acting for or employed by any corporation * * * within

[7] See "A Treatise on the Law of Food, Drugs and Cosmetics," 1942, p. 737; Law & Contemporary Problems, published by the School of Law of Duke University, 1939, Vol. 6, p. 74.

the scope of his employment or office, shall in every case be also deemed to be the act, omission or failure of such corporation * * * as well as that of the person.' In our opinion the omission of this provision adds nothing to the argument already developed; it was doubtless omitted as unnecessary because it states an obvious general principle of agency.

"The foregoing discussion has proceeded upon the assumption that if the statute is applicable to the appellant it must also apply to a shipping clerk or any menial employee who was instrumental in causing the forbidden shipment, for we can find no basis in the statutory language for drawing a distinction between agents of high or low rank. We are not, however, to be understood to hold that under no circumstances could an individual conducting a drug business in corporate form be subjected to the penalties of section 331 (a). If an individual operated a corporation as his 'alter ego' or agent he might be the principal; but the evidence hardly went so far as to establish that such was the relationship between the appellant and his corporation and in any event his guilt was not made to turn on any such issue. Accordingly his conviction must be reversed.

"The views above expressed in respect to the construction of the statute are those of a majority of the court. I am not in accord with them. I believe that the language of sections 331 (a) and 333 (a) is so inclusive as to render liable all persons who take part in causing a shipment in interstate commerce of misbranded or adulterated articles, and that any insufficiency in the protection afforded an agent by section 333 (c) is not an adequate reason for limiting the statutory prohibitions to the dealer. The possibility that a literal interpretation of the statute may lead to the prosecution of insignificant agents rather than their employers is not, I believe, a serious risk and is a matter Congress was willing to leave to the good sense of prosecuting officials and trial juries. See *United States* v. *Buffalo Cold Storage Co.*, 179 F. 865, 867 (D. C. W. D. N. Y.), where a warehouseman who innocently shipped pursuant to instructions was convicted under the 1906 Act; see also the charge given by Judge Grubb in United States v. Mayfield, 177 F. 765 (D. C. Ala.).

"Judgment reversed."

On January 3, 1943, a petition for a rehearing was denied by the Circuit Court of Appeals and on February 8, 1943, a petition for a Writ of Certiorari was filed with the United States Supreme Court. Such petition was granted on April 5, 1943, and on November 22, 1943, the Supreme Court rendered the following opinion, which reversed the judgment of the Circuit Court of Appeals:

FRANKFURTER, *Associate Justice:* This was a prosecution begun by two informations, consolidated for trial, charging Buffalo Pharmacal Company, Inc., and Dotterweich, its president and general manager, with violations of the Act of Congress of June, 1938, c. 675, 52 Stat. 1040, 21 U. S. C. §§ 301–392, known as the Federal Food, Drug, and Cosmetic Act. The Company, a jobber in drugs, purchased them from their manufacturers and shipped them, repacked under its own label, in interstate commerce. (No question is raised in this case regarding the implications that may properly arise when, although the manufacturer gives the jobber a guaranty, the latter through his own label makes representations.) The informations were based on § 301 of that Act (21 U. S. C. § 331), paragraph (a) of which prohibits 'The introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adultered or misbranded'. 'Any person' violating this provision is, by paragraph (a) of § 303 (21 U. S. C. § 333), made 'guilty of a misdemeanor'. Three counts were to the jury—two, for shipping misbranded drugs in interstate commerce, and a third, for so shipping an adulterated drug. The jury disagreed as to the corporation and found Dotterweich guilty on all three counts. We start with the finding of the Circuit Court of Appeals that the evidence was adequate to support the verdict of adulteration and misbranding. 131 F. 2d 500, 502.

Two other questions which the Circuit Court of Appeals decided against Dotterweich call only for summary disposition to clear the path for the main question before us. He invoked § 305 of the Act requiring the Administrator, before reporting a violation for prosecution by a United States attorney, to give the suspect an 'opportunity to present his views'. We agree with the Circuit Court of Appeals that the giving of such an opportunity, which was not accorded to Dotterweich, is not a prerequisite to prosecution. This Court so held in *United States* v. *Morgan*, 222 U. S. 274, in construing the Food and Drugs Act of 1906, 34 Stat. 768, and the legislative history to which the court below called attention abundantly proves that Congress, in the changed phraseology of 1938, did not intend to introduce a change of substance. 83 Cong. Rec. 7792-94. Equally base-

less is the claim of Dotterweich that, having failed to find the corporation guilty, the jury could not find him guilty. Whether the jury's verdict was the result of carelessness or compromise or a belief that the responsible individual should suffer the penalty instead of merely increasing, as it were, the cost of running the business of the corporation, is immaterial. Juries may indulge in precisely such motives or vagaries. *Dunn* v. *United States*, 284 U. S. 390.

"And so we are brought to our real problem. The Circuit Court of Appeals, one judge dissenting, reversed the conviction on the ground that only the corporation was the 'person' subject to prosecution unless, perchance, Buffalo Pharmacal was a counterfeit corporation serving as a screen for Dotterweich. On that issue, after rehearing, it remanded the cause for a new trial. We then brought the case here, on the Government's petition for certiorari, 318 U. S. 753, because this construction raised questions of importance in the enforcement of the Federal Food, Drug, and Cosmetic Act.

"The court below drew its conclusion not from the provisions defining the offenses on which this prosecution was based (§§ 301 (a) and 303 (a)), but from the terms of § 303 (c). That section affords immunity from prosecution if certain conditions are satisfied. The condition relevant to this case is a guaranty from the seller of the innocence of his product. So far as here relevant, the provision for an immunizing guaranty is as follows: 'No person shall be subject to the penalties of subsection (a) of this section . . . (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act . . .'

"The Circuit Court of Appeals found it 'difficult to believe that Congress expected ayone except the principal to get such a guaranty, or to make the guilt of an agent depend upon whether his employer had gotten one.' 131 F. 2d 500, 503. And so it cut down the scope of the penalizing provisions of the Act to the restrictive view, as a matter of language and policy, it took of the relieving effect of a guaranty.

"The guaranty clause cannot be read in isolation. The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. See *Hipolite Egg Co.* v. *United States*, 220 U. S. 45, 57, and *McDermott* v. *Wisconsin*, 228 U. S. 115, 128. The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. *United States* v. *Balint*, 258 U. S. 250. And so it is clear that shipments like those now in issue are 'punished by the statute if the article is misbranded [or adulterated], and that the article may be misbranded [or adulterated] without any conscious fraud at all. It was natural enough to throw this risk on shippers with regard to the identity of their wares. . . .' *United States* v. *Johnson*, 221 U. S. 488, 497–98.

"The statute makes 'any person' who violates § 301(a) guilty of a 'misdemeanor'. It specifically defines 'person' to include 'corporation'. § 201(e). But the only way in which a corporation can act is through the individuals who act on its behalf. *New York Central R. R.* v. *United States*, 212 U. S. 481. And the historic conception of a 'misdemeanor' makes all those resposible for it equally guilty, *United States* v. *Mills*, 7 Pet. 138, 141, a doctrine given general application in § 332 of the Penal Code (18 U. S. C. § 550). If, then, Dotterweich is not subject to the Act, it must be solely on the ground that individuals are immune when the 'person' who violates § 301(a) is a corporation, although from the point of view of action the individuals are the corporation. As a matter of

legal development, it has taken time to establish criminal liability also for a corporation and not merely for its agents. See *New York Central R. R.* v. *United States*, *supra*. The history of federal food and drug legislation is a good illustration of the elaborate phrasing that was in earlier days deemed necessary to fasten criminal liability on corporations. Section 12 of the Food and Drugs Act of 1906 provided that, 'the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be, also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person.' By 1938, legal understanding and practice had rendered such statement of the obvious superfluous. Deletion of words—in the interest of brevity and good draftsmanship [8]—superfluous for holding a corporation criminally liable can hardly be found ground for relieving from such liability the individual agents of the corporation. To hold that the Act of 1938 freed all individuals, except when proprietors, from the culpability under which the earlier legislation had placed them is to defeat the very object of the new Act. Nothing is clearer than that the later legislation was designed to enlarge and stiffen the penal net and not to narrow and loosen it. This purpose was unequivocally avowed by the two committees which reported the bills to the Congress. The House Committee reported that the Act 'seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906'. (H. Rep. No. 2139, 75th Cong., 3d Sess., p. 1.) And the Senate Committee explicitly pointed out that the new legislation 'must not weaken the existing laws', but on the contrary 'it must strengthen and extend that law's protection of the consumer.' (S. Rep. No. 152, 75th Cong., 1st Sess., p. 1.) If the 1938 Act were construed as it was below, the penalties of the law could be imposed only in the rare case where the corporation is merely an individual's *alter ego*. Corporations carrying on an illicit trade would be subject only to what the House Committee described as a 'license fee for the conduct of an illegitimate business.' [9] A corporate officer, who even with 'intent to defraud or mislead (§ 303b), introduced adulterated or misbranded drugs into interstate commerce could not be held culpable for conduct which was indubitably outlawed by the 1906 Act. See, e. g., *United States* v. *Mayfield*, 177 F. 765. This argument proves too much. It is not credible that Congress should by implication have exonerated what is probably a preponderant number of persons involved in acts of disobedience—for the number of non-corporate proprietors is relatively small. Congress, of course, could reverse the process and hold only the corporation and allow its agents to escape. In very exceptional circumstances it may have required this result. See *Sherman* v. *United States*, 282 U. S. 25. But the history of the present Act, its purposes, its terms, and extended practical construction lead away from such a result once 'we free our minds from the notion that criminal statutes must be construed by some artificial and conventional rule'. *United States* v. *Union Supply Co.*, 215 U. S. 50, 55.

"The Act is concerned not with the proprietory relation to a misbranded or an adulterated drug but with its distribution. In the case of a corporation such distribution must be accomplished, and may be furthered, by persons standing in various relations to the incorporeal proprietor. If a guaranty immunizes shipments of course it immunizes all involved in the shipment. But simply because if there has been a guaranty it would have been received by the proprietor, whether corporate or individual, as a safeguard for the enterprise, the want of a guaranty does not cut down the scope of responsibility of all who are concerned with transactions forbidden by § 301. To be sure, that casts the risk that there is no guaranty upon all who according to settled doctrines of criminal law are responsible for the commission of a misdemeanor. To read the guaranty section, as did the court below, so as to restrict liability for penalties to the only person who normally would receive a guaranty—the proprietor—disregards the admonition that 'the meaning of a sentence is to be felt rather than to be proved'. *United States* v. *Johnson*, 221 U. S. 488, 496. It also reads an exception to an important provision safeguarding the public welfare with a

[8] 'The bill has been made shorter and less verbose than previous bills. That has been done without deleting any effective provisions.' S. Rep. No. 152, 75th Cong., 1st Sess., p. 2

[9] In describing the penalty provisions of § 303, the House Committee reported that the Bill 'increases substantially the criminal penalties which some manufacturers have regarded as substantially a license fee for the conduct of an illegimate business.' H. Rep. No. 2139, 75th Cong., 3d Sess., p. 4.

liberality which more appropriately belongs to enforcement of the central purpose of the Act.

"The Circuit Court of Appeals was evidently tempted to make such a devitalizing use of the guaranty provision through fear that an enforcement of § 301(a) as written might operate too harshly by sweeping within its condemnation any person however remotely entangled in the proscribed shipment. But that is not the way to read legislation. Literalism and evisceration are equally to be avoided. To speak with technical accuracy, under § 301 a corporation may commit an offense and all persons who aid and abet its commission are equally guilty. Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance. The offense is committed, unless the enterprise which they are serving enjoys the immunity of a guaranty, by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws, namely to put into the stream of interstate commerce adulterated or misbranded drugs. Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.

"It would be too treacherous to define or even to indicate by way of illustration the class of employees which stands in such a responsible relation. To attempt a formula embracing the variety of conduct whereby persons may responsibly contribute in furthering a transaction forbidden by an Act of Congress, to wit, to send illicit goods across state lines, would be mischievous futility. In such matters the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted. Our system of criminal justice necessarily depends on 'conscience and circumspection in prosecuting officers.' *Nash* v. *United States*, 229 U. S. 373, 378 even when the consequences are far more drastic than they are under the provision of law before us. See *United States* v. *Balint*, *supra* (involving a maximum sentence of five years). For present purpose it suffices to say that in what the defense characterized as 'a very fair charge' the District Court properly left the question of the responsibility of Dotterweich for the shipment to the jury, and there was sufficient evidence to support its verdict."

Judgment reversed.

MURPHY, *Associate Justice*, dissenting: "Our prime concern in this case is whether the criminal sanctions of the Federal Food, Drug, and Cosmetic Act of 1938 plainly and unmistakenly apply to the respondent in his capacity as a corporate officer. He is charged with violating § 301(a) of the Act, which prohibits the introduction or delivery for introduction into interstate commerce of any adulterated or misbranded drug. There is no evidence in this case of any personal guilt on the part of the respondent. There is no proof or claim that he ever knew of the introduction into commerce of the adulterated drugs in question, much less that he actively participated in their introduction. Guilt is imputed to the respondent solely on the basis of his authority and responsibilty as president and general manager of the corporation.

"It is a fundamental principle of Anglo-Saxon jurisprudence that guilt is personal and that it ought not lightly to be imputed to a citizen who, like the respondent, has no evil intention or consciousness of wrongdoing. It may be proper to charge him with responsibility to the corporation and the stockholders for negligence and mismanagement. But in the absence of clear statutory authorization it is inconsistent with established canons of criminal law to rest liability on an act in which the accused did not participate and of which he had no personal knowledge. Before we place the stigma of a criminal conviction upon any such citizen the legislative mandate must be clear and unambiguous. Accordingly that which Chief Justice Marshall has called 'the tenderness of the law for the rights of individuals'[10] entitles each person, regardless of economic or social status, to an unequivocal warning from the legislature as to whether he is within the class of persons subject to vicarious liability. Congress cannot be deemed to have intended to punish anyone who is not 'plainly and unmistakably'

[10] United States v. Wiltberger, 5 Wheat, 76, 95.

within the confines of the statute. *United States* v. *Lacher*, 134 U. S. 624, 628; *United States* v. *Gradwell*, 243 U. S. 476, 485.

"Moreover, the fact that individual liability of corporate officers may be consistent with the policy and purpose of a public health and welfare measure does not authorize this Court to impose such liability where Congress has not clearly intended or actually done so. Congress alone has the power to define a crime and to specify the offenders. *United States* v. *Wiltberger*, 5 Wheat. 76, 95. It is not our function to supply any deficiencies in these respects, no matter how grave the consequences. Statutory policy and purpose are not constitutional substitutes for the requirement that the legislature specify with reasonable certainty those individuals it desires to place under the interdict of the Act. *United States* v. *Harris*, 177 U. S. 305; *Sarlls* v. *United States*, 152 U. S. 570.

"Looking at the language actually used in this statute, we find a complete absence of any reference to corporate officers. There is merely a provision in § 303(a) to the effect that 'any person' inadvertently violating § 301(a) shall be guilty of a misdemeanor. Section 201(e) further defines 'person' as including an 'individual, partnership, corporation, and association.[11]' The fact that a corporate officer is both a 'person' and an 'individual' is not indicative of an intent to place vicarious liability on the officer. Such words must be read in light of their statutory environment.[12] Only if Congress has otherwise specified an intent to place corporate officers within the ambit of the Act can they be said to be embraced within the meaning of the words 'person' or 'individual' as here used.

Nor does the clear imposition of liability on corporations reveal the necessary intent to place criminal sanctions on their officers. A corporation is not the necessary and inevitable equivalent of its officers for all purposes.[13] In many respects it is desirable to distinguish the latter from the corporate entity and to impose liability only on the corporation. In this respect it is significant that this Court has never held the imposition of liability on a corporation sufficient, without more, to extend liability to its officers who have no consciousness of wrongdoing.[14] Indeed, in a closely analogous situation, we have held that the vicarious personal liability of receivers in actual charge and control of a corporation could not be predicated on the statutory liability of a 'company,' even when the policy and purpose of the enactment were consistent with personal liability. *United States* v. *Harris, supra*.[15] It follows that express statutory provisions are necessary to

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[11] The normal and necessary meaning of such a definition of 'person' is to distinguish between individual enterprises and those enterprises that are incorporated or operated as a partnership or association, in order to subject them to the Act. This phrase cannot be considered as an attempt to distinguish between individual officers of a corporation and the corporate entity. Lee, 'Corporate Criminal Liability,' 28 Col. L. Rev. 1, 181, 190.

[12] Compare United States *v.* Cooper Corp., 312 U. S. 600, 606, and Davis *v.* Pringle, 268 U. S. 315, 318, holding that the context and legislative history of the particular statutes there involved indicated that the words "any person" did not include the United States. But in Georgia *v.* Evans, 316 U. S. 159, and Ohio *v.* Helvering, 292 U. S. 360, these considerations led to the conclusion that 'any person' did include a state. See also 40 Stat. 1143, which specifically includes officers within the meaning of 'any person' as used in the Revenue Act of 1918.

[13] In Park Bank v. Remsen, 158 U. S. 337, 344, this Court said, 'It is the corporation which is given the powers and privileges and made subject to the liabilities. Does this carry with it an imposition of liability upon the trustee or other officer of the corporation? The officer is not the corporation; his liability is personal, and not that of the corporation, nor can it be counted among the powers and privileges of the corporation.'

[14] For an analysis of the confusion on this matter in the state and lower federal courts, see Lee, 'Corporate Criminal Liability,' 28 Col. L. Rev. 1, 181.

[15] In that case we had before us Rev. Stat. §§ 4386–4389, which penalized 'any company, owner or custodian of such animals' who failed to comply with the statutory requirements as to livestock transportation. A railroad company violated the statute and the government sought to impose liability on the receivers who were in actual charge of the company. It was argued that the word 'company' embraced the natural persons acting on behalf of the company and that to hold such officers and receivers liable was within the policy and purpose of so humane a statute. We rejected this contention in language peculiarly appropriate to this case (177 U. S. at 309):

'It must be admitted that, in order to hold the receivers, they must be regarded as included in the word 'company.' Only by a strained and artificial construction, based chiefly upon a consideration of the mischief which the legislature sought to remedy, can receivers be brought within the terms of the law. But can such a kind of construction be resorted to in enforcing a penal statute? Giving all proper force to the contention of counsel of the government, that there has been some relaxation on the part of the courts in applying the rule of strict construction to such statutes, it still remains that the intention of a penal statute must be found in the language actually used, interpreted according to its fair and obvious meaning. It is not permitted to courts, in this class of cases, to attribute inadvertence or oversight to the legislature when enumerating the classes of persons who are subjected to a penal enactment, nor to depart from the settled meaning of words or phrases in order to bring persons not named or distinctly described within the supposed purpose of the statute.'

satisfy the requirement that officers as individuals be given clear and unmistakable warning as to their vicarious personal liability. This Act gives no such warning.

"This fatal hiatus in the Act is further emphasized by the ability of Congress, demonstrated on many occasions, to apply statutes in no uncertain terms to corporate officers as distinct from corporations.[16] The failure to mention officers specifically is thus some indication of a desire to exempt them from liability. In fact the history of federal food and drug legislation is itself illustrative of this capacity for specification and lends strong support to the conclusion that Congress did not intend to impose liability on corporate officers in this particular Act.

"Section 2 of the Federal Food and Drugs Act of 1906, as introduced and passed in the Senate, contained a provision to the effect that any violation of the Act by a corporation should be deemed to be the act of the officer responsible therefor and that such officer might be punished as though it were his personal act.[17] This clear imposition of criminal responsibility on corporate officers, however, was not carried over into the statute as finally enacted. In its place appeared merely the provision that 'when construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation . . . within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation , . . as well as that of the person.' [18] This provision had the effect only of making corporations responsible for the illegal acts of their officers and proved unnecessary in view of the clarity of the law to that effect. *New York Central & H. R. R. Co.* v. *United States*, 212 U. S. 481.

"The framers of the 1938 Act were aware that the 1906 Act was deficient in that it failed 'to place responsibility properly upon corporate officers.' [19] In order 'to provide the additional scope necessary to prevent the use of the corporate form as a shield to individual wrongdoers,' [20] these framers inserted a clear provision that 'whenever a corporation or association violates any of the provisions of this Act, such violation shall also be deemed to be a violation of the individual directors, officers, or agents of such corporation or association who authorized, ordered, or did any of the acts constituting, in whole or in part, such violation.' [21] This paragraph, however, was deleted from the final version of the Act.

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[16] "Whenever a corporation shall violate any of the penal provisions of the antitrust laws, such violation shall be deemed to be also that of the individual directors, officers, or agents of such corporation who shall have authorized, ordered, or done any of the acts constituting in whole or in part such violation." 15 U. S. C. § 24.

"The courts of bankruptcy . . . are invested . . . with such jurisdiction at law and in equity as will enable them to . . . (4) arraign, try, and punish bankrupts, officers, and other persons, and the agents, officers, members of the board of directors or trustees, or other similar controlling bodies, of corporations for violations of the provisions contained in this title." 11 U. S. C. § 11.

"Any such common carrier, or any officer or agent thereof, requiring or permitting any employee to go, be, or remain on duty in violation of the next preceding section of this chapter shall be liable to a penalty . . ." 45 U. S. C. § 63.

"A mortgagor who, with intent to defraud, violates any provision of subsection F, section 924, and if the mortgagor is a corporation or association, the president or other principal executive officer of the corporation or association, shall upon conviction thereof be held guilty of a misdemeanor . . ." 46 U. S. C. § 941 (b).

[17] S. 88, 59th Cong., 1st Sess. Senator Heyburn, one of the sponsors of S. 88, stated that this was "a new feature in bills of this kind. It was intended to obviate the possibility of escape by officers of a corporation under a plea, which has been more than once made, that they did not know that this was being done on the credit of or on the responsibility of the corporation." 40 Cong. Rec. 894.

[18] 34 Stat. 772, 21 U. S. C. § 4.

[19] Senate Report No. 493, 73d Cong., 2d Sess., p. 21.

[20] *Ibid.*, p. 22. This report also stated that "it is not, however, the purpose of this paragraph to subject to liability those directors, officers, and employees, who merely authorize their subordinates to perform lawful duties and such subordinates, on their own initiative, perform those duties in a manner which violates the provisions of the law. However, if a director or officer personally orders his subordinate to do an act in violation of the law, there is no reason why he should be shielded from personal responsibility merely because the act was done by another and on behalf of a corporation."

[21] This provision appears in several of the early versions of the Act introduced in Congress. S. 1944, 73d Cong., 1st Sess., § 18(b) ; S. 2000, 73d Cong., 2d Sess., § 18(b) ; S. 2800, 73d Cong., 2d Sess., § 18(b) ; S. 5, 74th Cong., 1st Sess., § 709(b) ; S. 5, 74th Cong., 2d Sess., § 707(b), as reported to the House, which substituted the word "personally" for the word "authorized" in the last clause of the paragraph quoted above. A variation of this provision appeared in S. 5, 75th Cong., 1st Sess., § 2(f), and made a marked distinction between the use of the word "person" and the words "director, officer, employee, or agent acting for or employed by any person." All of these bills also contained the present definition of "person" as including "individual, partnership, corporation, and association."

"We cannot presume that this omission was inadvertent on the part of Congress. *United States* v. *Harris*, *supra* at 309. Even if it were, courts have no power to remedy so serious a defect, no matter how probable it otherwise may appear that Congress intended to include officers; 'probability is not a guide which a court, in construing a penal statute, can safely take.' *United States* v. *Wiltberger*, *supra* at 105. But the framers of the 1938 Act had an intelligent comprehension of the inadequacies of the 1906 Act and of the unsettled state of the law. They recognized the necessity of inserting clear and unmistakable language in order to impose liability on corporate officers. It is thus unreasonable to assume that the omission of such language was due to a belief that the Act as it now stands was sufficient to impose liability on corporate officers. Such deliberate deletion is consistent only with an intent to allow such officers to remain free from criminal liability. Thus to apply the sanctions of this Act to the respondent would be contrary to the intent of Congress as expressed in the statutory language and in the legislative history.

"The dangers inherent in any attempt to create liability without express Congressional intention or authorization are illustrated by this case. Without any legislative guides, we are confronted with the problem of determining precisely which officers, employees and agents of a corporation are to be subject to this Act by our fiat. To erect standards of responsibility is a difficult legislative task and the opinion of this Court admits that it is 'too treacherous' and a 'mischievous futility' for us to engage in such pursuits. But the only alternative is a blind resort to 'the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries.' Yet that situation is precisely what our constitutional system sought to avoid. Reliance on the legislature to define crimes and criminals distinguishes our form of jurisprudence from certain less desirable ones. The legislative power to restrain the liberty and to imperil the good reputation of citizens must not rest upon the variable attitudes and opinions of those charged with the duties of interpreting and enforcing the mandates of the law. I therefore cannot approve the decision of the Court in this case.

"Mr. Justice ROBERTS. Mr. Justice REED and Mr. Justice RUTLEDGE join in this dissent."

918. Adulteration and misbranding of elixir phenobarital. U. S. v. The Liebenthal Brothers Co. (Marlo Products Co.). Plea of guilty. Fine, $500 and costs. (F. D. C. No. 7274. Sample No. 71157–E.)

This product was sold under a name recognized in the National Formulary, an official compendium, and differed in strength and quality from the standard prescribed in such authority.

On August 21, 1942, the United States attorney for the Northern District of Ohio filed an information against the Liebenthal Brothers Co., a corporation, trading under the name of Marlo Products Co., Cleveland, Ohio, alleging shipment on or about December 18, 1941, from the State of Ohio into the State of Missouri of a quantity of elixir phenobarbital which was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which, elixir of phenobarbital, is recognized in the National Formulary, an official compendium, and its strength differed from and its quality fell below the standard set forth therein since it contained not more than 0.107 gram of phenobarbital in each 100 cc., whereas the Formulary provides that elixir of phenobarbital shall contain not less than 0.37 gram of phenobarbital in each 100 cc.; and its difference in strength and quality from the standard set forth in the compendium was not plainly stated on its label.

It was alleged to be misbranded in that the statement, "Elixir Phenobarbital N. F. * * * Each fluid ounce contains 1.83 grains Phenobarbital," borne on its label, was false and misleading since the statement represented that the article consisted of elixir of phenobarbital which complied with the requirements of the National Formulary and that each fluid ounce thereof contained 1.83 grains of phenobarbital, whereas the article did not consist of elixir of phenobarbital which complied with such requirements, and each fluid ounce thereof contained not more than 0.49 grain of phenobarbital.

On April 13, 1943, the defendant having entered a plea of guilty, the court imposed a fine of $500 and costs.

919. Adulteration and misbranding of Hain Abgede Capsules. U. S. v. Harold Hain (Hain Pure Food Co.) Plea of not guilty. Tried to the court. Judgment of guilty. Fine, $200, $100 of which was suspended. (F. D. C. No. 4154. Sample No. 32640–E.)

On September 10, 1941, the United States attorney for the Southern District of California filed an information against Harold Hain, trading as the Hain Pure Food Co., Los Angeles, Calif., alleging shipment on or about October 11, 1940, from the State of California into the State of Arizona of a quantity of Hain Abgede which was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from or its quality fell below that which it purported or was represented to possess, since it was represented to contain in each capsule 25 international units of vitamin B_1, equivalent to 45 Sherman units of vitamin B_1, whereas it contained in each capsule not more than 15 international units of vitamin B_1, equivalent to not more than 27 Sherman units of vitamin B_1.

It was alleged to be misbranded in that the statement, "Each Capsule Contains Not Less Than * * * Vitamin B_1—45 Sherman (25 Int.) units," borne on the boxes containing the article, was false and misleading since it contained not more than 15 international units of vitamin B_1, equivalent to not more than 27 Sherman units of vitamin B_1. It was alleged to be misbranded further in that the statement "Vitamins A B_1 G D," borne on the boxes, was misleading since it represented that the article contained therapeutic amounts of vitamins B_1 and G, whereas the article, when taken in the maximum dosage recommended and suggested, namely, 2 capsules per day, would supply not more than $\frac{1}{10}$ of the average therapeutic dose of vitamin B_1, and not more than $\frac{1}{40}$ of the amount of vitamin G required daily by an adult, which amounts of vitamins B_1 and G would be inconsequential for therapeutic purposes.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods reported in food notices of judgment.

On September 29, 1941, the defendant entered a plea of not guilty. On April 15, 1943, the case having come on before the court on a stipulation of facts and briefs submitted by the counsel for the defendant and the Government, the defendant was adjudged guilty and fined $200 on the 2 counts involving violation of the provisions of the law applicable to drugs, $100 of which, however, was suspended, and not guilty on the counts charging violation of the provisions applicable to foods. In announcing his decision, the court delivered the following memorandum opinion:

JENNEY, *District Judge:* "This is a criminal prosecution by the United States against Harold Hain, trading as the Hain Pure Food Company, for the violation of the Federal Food, Drug, and Cosmetic Act of 1938 (52 Statutes at Large 1040).

"The case is before the court under a stipulation of facts.

"In essence, the facts are as follows:

"The Defendant purchased a quantity of vitamin capsules from the International Vitamin Corporation of New York, which company manufactured, packaged, and labeled them. These were shipped to the defendant at his place of business in Los Angeles, in April 1939. Later, in June 1940, defendant obtained a guarantee from the International Vitamin Corporation assuring compliance with the Federal Food, Drug, and Cosmetic Act of any vitamin products they might sell to the defendant.

"In October 1940, defendant sold and shipped a quantity of these vitamin capsules in interstate commerce.

"In November 1940, a sample was taken from this shipment, which was tested and analyzed by an agent of the Food and Drug Administration. The vitamin potency, in respect to vitamin B_1, was found to be substantially below that represented on the labels of the boxes containing the capsules.

"The defendant did not alter the contents of the vitamin capsules, the contents of the boxes, nor the labels on the boxes.

"The information charges defendant with the violation of the Federal Food, Drug and Cosmetic Act of 1938 (Hereafter called, the Act), in four counts.

"The first count charges that the defendant delivered into interstate commerce an *adulterated food* in violation of the act.

"The third count charges that the defendant *misbranded* a *food* in violation of the act.

"The second count charges that the defendant delivered into interstate commerce an *adulterated drug* in violation of the Act.

"The fourth count charges that the defendant *misbranded* a *drug* in violation of the Act.

"These will be discussed in the order just stated.

"The apparent reason for drafting the information in four counts, and thereby presenting duplicate charges against the defendant—one based on a violation of the Act in respect to food, and the other in respect to drugs—is that there is a question as to whether concentrated vitamins in capsules are to be considered as a food or as a drug.

"The commercial use of concentrated vitamins in the fields of medicine and dietetics is a comparatively recent innovation. Experts in these fields disagree as to the category in which such vitamins are to be classed. However, it is not necessary for us to go into the subject extensively. Our inquiry is limited to the question of how vitamins should be classified solely in applying the provisions of the Act. In doing so, our first inquiry directs us to the definitions in the Act itself.

"In *21 U. S. C. A. 321 (g)*, it is stated: 'For the purposes of this chapter the term 'Drug' means (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the U. S., *or* official National Formulary, . . .'

"The following vitamins are so recognized and listed in the Pharmacopoeia of the United States, 12th Revision, 1943: Vitamins A, B_1, C, D, D_2, D_3, and G.

"It is seen, therefore, that vitamins fall within the definition of 'drugs' insofar as the application of the Act is concerned. It is therefore immaterial in the determination of the case at bar how they are classified for other purposes.

"This interpretation is supported by the case of *United States v. Frank*, 189 Fed. 195, (1911). Here the court in interpreting a section similar to ours in the 1906 Food and Drug Act states at page 199: 'Section 6 of the Act of 1906 provides: "That the term 'drug' as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of diseases of either man or other animals . . ." These are mere terms of description. If the Pharmacopoeia or National Formulary says something is a drug, it is a drug under the meaning of the Act. . . .'

"The classification of vitamins as 'drugs' is logical in the light of analogous cases. This is well exemplified by the case of *Goodwin v. United States* (C. C. A., 6th Circuit) 2 Fed. (2nd) 200, where the court held that mineral water transported, not being in its original state, and processes of separation of the constituent drug elements being carried to the extent that the commercial water can no longer be used as a beverage, but only in small quantities as a drug, it is to be classified as a 'drug', and not a 'food', within the Food and Drug Act.

"We shall therefore deem concentrated vitamins as 'drugs' in the application of the Act before us.

"Since these vitamin products are 'drugs', count one and count three of the information are unsupported by the facts.

"Therefore, defendant is found not guilty as to counts one and three of the information.

"The allegations of violations of the Act in counts two and four, respectively, are concerned with the unlawful shipping of adulterated drugs in interstate commerce, and with the unlawful shipping of misbranded drugs in interstate commerce.

"In order that the prosecution may make out a prima facie case it is only necessary to show that defendant violated the express requirements of the Act. Good faith does not enter into the matter.

"*Strong, Cobb and Co.* v. *United States*, 103 Fed. (2d) 671. Here it was held that in a prosecution for shipment in interstate commerce of adulterated cold tablets in violation of the Federal Food, Drug and Cosmetic Act, *intent of defendant was not material*, since statute requires specific statements as to content of acetanilid compound.

"In *'Law of Foods, Drugs, and Cosmetics'* by Toulman, 1942 Edition, it is stated on page 75,: 'By the terms of the 1938 Act, good faith is a defence in criminal prosecution, when the charge is the *receiving* of adulterated or misbranded goods in interstate commerce. The good faith exemption does not apply when the charge is the *shipping* of misbranded or adulterated goods in interstate commerce. Therefore, intent, or something very like intent, must be proved by the government to secure a conviction when there is instituted a criminal prosecution for the receiving of adulterated or misbranded goods in interstate commerce. By implication, the new law *does not require intent to be proved* in cases where

there is instituted a criminal prosecution for the *shipping* of adulterated or misbranded goods in interstate commerce.'

"The sections of the Food and Drug Act involved here are:

"21 U. S. C. 331 (a), which states: 'The following acts and the causing thereof are hereby prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.'

"21 U. S. C. 351 (c), which states: 'A drug or device shall be deemed to be adulterated if it is not subject to the provisions of paragraph (b) of this section and its strength differs from or its purity or quality falls below, that which it purports or is represented to possess.'

"21 U. S. C. 352 (a), states: 'A drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular.'

"It is readily seen that these statutes cover the stipulated facts in our case, and it is therefore unnecessary to repeat them.

"Therefore, a prima facie case has been made out by the Government against the defendant on both counts.

"However, the Act permits a defense to prosecution thereunder if a valid 'guaranty' has been obtained.

"This is set forth in 21 U. S. C. 333 (c), which states, 'No person shall be subject to the penalties of subscrion (a) of this section (2) for having violated section 331 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 221 (a),that such article is not adulterated or misbranded, within the meaning of this chapter, designating this chapter, or to the effect, in case of an alleged violation of section 331 (d), that such article is not an article which may not, under the provisions of section 344 or 355, be introduced into interstate commerce; . . .'

"In our case a purported guaranty was obtained fourteen months after acquiring the product.

"It is within the promise of the court to determine the legal meaning of documents.

"In *United States v. Glaser, etc.* (C. C. A. 7) 224 Fed. 84, it was held that the question of whether or not a given instrument in writing is a guaranty is a question of law, to be decided by the court.

"Therefore, the question as to whether this guaranty is valid, as being within the foregoing section and therefore exempting the defendant from liability is a question of law for the court to determine from the document.

"The object of this portion of the Act is to shift criminal responsibility rather than to absolve all parties therefrom. The reason for this is that the primary purpose of the Act is the protection of the public. It is only secondarily concerned with the question of the identity of the person who is to bear the brunt of the burden—i. e. between the manufacturer and the retailer—so long as there is positive responsibility in some party. This interpretation is supported by *Steinhardt Bros. and Co. v. United States* (C. C. A. 2nd). 191 Federal 798., *United States v. Antikammia Co.*, 231 U. S. 654.

"In *United States* v. *Mayfield*, et al., 177 Fed. 765, the court in construing the counterpart of our section in the 1906 Food and Drug Act, states: "The ninth section provides that no dealer shall be prosecuted under the provisions of the Act, when he can establish a guaranty, signed by the manufacturer from whom he purchased such articles, to the effect that the same article is not adulterated or misbranded within the meaning of the act; in which case, the manufacturer shall be amenable to the prosecutions, fines, and other penalties, which would otherwise attach to the dealer. The purpose of Congress was to place liability for the violation of the law upon some one in each instance. Primarily the liability is on the dealer who introduces the article into interstate commerce. The liability can be shifted from the dealer only by imposing the same liability upon the manufacturer. This can be done only by virtue of the manufacturer's guaranty to the dealer. If, for any reason, the guaranty is insufficient to impose liability upon the manufacturer, it remains where it primarily rested—upon the dealer. To have the effect of releasing the dealer from liability for the violation of the act, complained of in this prosecution, the guaranty must be of a character to impose liability for the same violation upon the manufacturer, if he were substituted for these defendants in this case; otherwise, both parties would escape liability, and the purpose expressed by Congress would be de-

feated. The act says that the manufacturer who signs the guaranty shall be subject to the same prosecution and penalties as the dealer. If a conviction could not be sustained against the manufacturer upon its guaranty, if substituted for the defendants in this case, then the taking of the guaranty by defendants would be no defense to their violation of the law in reference to the shipment in question, though they had no knowledge that it was adulterated or misbranded.'

"Therefore, in order for the defendant to be absolved of liability he must comply clearly with the Act.

"Here, Exhibit 'A' is claimed by defendant to be such a guaranty.

"The guaranty states that the International Vitamin Corporation guarantees that no food, drug, etc., 'now or hereafter' made for defendant will 'at the time of such shipment' be adulterated or misbranded within the meaning of the Act. Further on, it states that, 'This guaranty shall be a continuing guaranty . . .'

"This guaranty was given after the goods in question here were sold and delivered to the defendant.

"In order for the guaranty to be valid as a defense, it must refer to the specific goods and the specific sale in question.

"As stated in United States v. Mayfield (supra), 'In order for the manufacturer's guaranty to be effective to impose any liability upon him for any violation of law as to the article, which is the basis of this prosecution, the guaranty must relate to the identical article introduced into interstate commerce by the defendants as dealers. Otherwise the answer of the manufacturer to the prosecution would be that he had never guaranteed the article shipped by the dealer, and the answer would be complete.'

"This is clearly not the case in this guaranty. The language is susceptible of only one interpretation—that the guaranty was to be a 'continuing guaranty,' effective only from the date given, on into the future. Its meaning clearly does not include a guaranty of any sales made in the past.

"The apparent postscript on the document is claimed to have a retroactive effect, and to throw the guaranty within the purview of the exemption section.

"The postscript reads, 'The above guarantee applies to all merchandise shipped by us against your contracts.' It is then signed by an unidentified 'F. Satz.'

"This language may possibly be ambiguous. However, construed in the light of the guarantee, it becomes apparent that it is capable of only one meaning. That is, that the guaranty is a continuing guarantee.

"However, assuming arguendo, that it meant all the defendant claims it means, it still would not help him. Two interpretations may be made of this postscript. One is that Satz is attempting to interpret the meaning of the guaranty; the other that Satz is attempting to supplement the legal liability of the corporation. The first view is of no effect here, because that is a question of law for the court to determine. The second view has no effect because there is no showing that Satz had authority to bind the corporation, or even that he was attempting to bind the corporation. Further, if he signed it with his personal backing, it is fatal because, as stated in Regulation (g) under 21 U. S. C. 303 (c), 'A guarantee or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.' This was not done here.

"Therefore, under any of the foregoing interpretations it is seen that there is no guaranty which would cover the goods in question.

"Because of the foregoing, this guaranty fails in its validity for the purpose of exempting the defendant from prosecution, and in effect is as though no guaranty at all were given. This eliminates any defense defendant might have in this respect.

"Defendant is found guilty of count two and count four as charged in the information.

"*The penalties under this act are:* (21 U. S. C. A. 333 (a), (b))

"(1) Imprisonment for not more than one year, a fine of not more than $1,000, or both, as for a misdemeanor.

"(2) If the accused has already been convicted once, under that statute, the penalty is imprisonment for not more than 3 years, and a fine of not more than $10,000, or both.

"(3) If the violation is with intent to defraud and mislead, the penalty is the same as if the accused had already been once convicted."

920. Adulteration and misbranding of Cow-Vet and misbranding of Willits ToneX, SprayX, and Powder WormX. U. S. v. G. D. Willits (G. D. Willits Co.). Plea of nolo contendere. Sentence suspended and defendant placed on probation for 6 months. (F. D. C. No. 7256. Sample Nos. 54269–E to 54271–E, incl., 54273–E.)

In addition to the false and misleading therapeutic claims in the labeling of these products, the strength of the Cow-Vet differed from that which it purported and was represented to possess.

On August 11, 1942, the United States attorney for the Middle District of Pennsylvania filed an information against G. D. Willits, trading as G. D. Willits Co., Salladasburg, Pa., alleging shipment on or about August 26, 1941, from the State of Pennsylvania into the State of New Jersey of quantities of the above-named drugs, all of which were misbranded, and one of which, the Cow-Vet, was also adulterated.

Analysis of a sample of the ToneX showed that it consisted essentially of small proportions of potassium chlorate, potassium dichromate, potassium nitrate, magnesium sulfate, and water.

It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that the drug was a wonderful conditioner of poultry, an antiseptic, a wonderful intestinal astringent, and was efficacious in the cure, mitigation, treatment, prevention, or removal of all types of worms from poultry; that it was a tonic; that it was scientifically compounded and would prevent disease in poultry; that it would cause poultry to drink more water and would thereby assist in the absorption of the yolk and would eliminate pasting; that it would tone up the entire digestive system, and was an effective conditioner of poultry; that it would be efficacious in the cure, mitigation, treatment, or prevention of coccidiosis and internal parasites; that it would aid in healing the intestinal lining of poultry and in flushing the mucous from the intestinal tract, and would be efficacious in the cure, mitigation, treatment, or prevention of common diarrhea in poultry; and that the article, in addition to other drug products of "The Willits XLine" of poultry and livestock health products, namely, "Willits SprayX," "Willits WormX Powder," and "Willits Cow-Vet," represented the latest developments in the control of poultry and livestock diseases; that it would promote the health of poultry; that it would assist in keeping the intestines of poultry healthy, and was efficacious in the cure, mitigation, treatment, prevention, or removal of roundworms and tapeworms; that it would be efficacious in the cure, mitigation, treatment, or prevention of colds and roup in poultry, and was efficacious in the cure, mitigation, treatment or prevention in poultry of droopy plumage, unthriftiness, pale combs and legs, drooping wings and emaciation, were false and misleading since the article would not be efficacious for the purposes represented.

Analysis of a sample of the SprayX showed that it consisted essentially of small proportions of volatile oils, including menthol and camphor incorporated in a base of mineral oil.

The SprayX was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that the article was efficacious for external and internal use as a soothing agent for the mucous membrane of the mouth, nostrils, throat, and eyes of poultry; that it was efficacious as an expectorant; and that, when used as directed, it was efficacious to loosen up canker conditions of the mouth; that it would prevent disease in poultry; that the article, in addition to other drug products of "The Willits X-Line" of poultry and livestock health products, as listed above, represented the latest developments in the control of poultry and livestock diseases; that the article was efficacious in the cure, mitigation, treatment, or prevention of colds in poultry and of injured or infected mucous membranes of the eyes, nostrils, mouth and throat of domestic poultry; and that it would be efficacious in the cure, mitigation, treatment or prevention of colds and roup in poultry, were false and misleading since the article was neither an article of the nature above-described, nor efficacious for the purposes represented.

Analysis of a sample of the Powder WormX showed that it consisted essentially of copper sulfate, iron sulfate, plant material including nux vomica and aniseed, and a small proportion of nicotine sulfate.

The Powder WormX was alleged to be misbranded in that the statements appearing in its labeling, which represented and suggested that the drug was a nicotine kamala combination and was efficacious for expelling large round ascaridia worms and desegmenting large tapeworms in chickens and turkeys; that it would promote health in poultry and would prevent losses; that, when

used as directed, the article was efficacious in the cure, mitigation, treatment, prevention, or removal of all types of worms in poultry; that it was scientifically compounded and would prevent disease in poultry; that it was efficacious in the cure, mitigation, treatment, or prevention of coccidiosis and internal parasites; that, when used as directed, it would desegment those species of tapeworms that cause an irritation to the intestinal lining and absorb those nutrients from the feed that are essential to the growth, development, and egg-producing organs of pullets; that it was efficacious in the cure, mitigation, treatment, prevention, or removal of tapeworms; that the article, in addition to other drug products of "The Willits X-Line" of poultry and livestock health products, represented the latest developments in the control of poultry and livestock diseases; that the article would expel ascaridia lineata and other forms of roundworms, and would desegment large tapeworms in chickens and turkeys; that it was efficacious in the cure, mitigation, treatment, or prevention in poultry of droopy plumage, unthriftiness, pale combs and legs, drooping wings, and emaciation were false and misleading since the article would not be efficacious for the purposes represented.

Analysis of a sample of the Cow-Vet showed that, in addition to not more than 0.178 percent of potassium iodide, it contained saltpeter, Epsom salt, and plant material, including nux vomica incorporated in a base of linseed meal.

The Cow-Vet was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that the article had been investigated and approved by competent animal research authorities; that it had a special tonic value; that it contained not less than 0.36 percent of potassium iodide; that it was a tonic for cows and a herd conditioner, and was an effective treatment for cows that would not conceive and for bulls that had become impotent; that it was scientifically compounded; that the article, in addition to other drug products of "The Willits X-Line" of poultry and livestock health products, represented the latest developments in the control of poultry and livestock diseases; that the article would stimulate and nourish the glands that control reproduction, food assimilation, and milk production; that the ingredients of the article had a definite function on the glands which control reproduction; that the article would supply vitamin E for dairy cattle and thereby correct breeding troubles; that it was efficacious in the treatment of colds of the urinary tract and of disease of the bladder; that it would increase perspiration in formative stages of colds and in muscular ailments due to colds; that it was efficacious in the treatment of uterine disorders such as after-pains and dysmenorrhea; and that it was a gentle tonic were false and misleading since the article contained less than 0.36 percent of potassium iodide and would not be efficacious for the purposes represented.

It was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess since the statement "Cow-Vet Contains * * * Potassium Iodide .36 percent," appearing on its label, represented and suggested that the article contained not less than .36 percent of potassium iodide, whereas it contained not more than 0.17 percent of potassium iodide.

On January 20, 1943, the defendant having entered a plea of nolle contendere, the court suspended the imposition of sentence and placed the defendant on probation for 6 months.

921. Adulteration of chorionic gonadotropic hormone. U. S. v. Abraham J. Blaivas, Murray Blaivas, Benjamin W. Feldman, and Emanuel Mandelbaum (Kings County Research Laboratories). Pleas of guilty. Fines of $100 against Benjamin W. Feldman, $300 against Murray Blaivas, and $500 each against Abraham J. Blaivas and Emanuel Mendelbaum. Sentence against each of the defendants of 6 months in prison suspended, and the defendants placed on probation for 18 months. (F. D. C. No. 7694. Sample No. 54941–E.)

This article differed from its declared standard of strength and quality.

On April 3, 1943, the United States attorney for the Eastern District of New York filed an information against Abraham J. Blaivas, Murray Blaivas, Benjamin W. Feldman, and Emanuel Mandelbaum, copartners trading as the Kings County Research Laboratories, Brooklyn, N. Y., alleging shipment on or about March 2, 1942, from the State of New York into the State of Pennsylvania of a quantity of chorionic gonadotropic hormone which was adulterated.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, viz., a physiological activity of 5,000 rat units (equivalent to approximately 6,000 international units) of chorionic gonadotropic hormone in each 10 cc., and anterior

pituitary-like sex hormone having a physiological activity of 500 rat units in each cubic centimeter, since it possessed a physiological activity, if any, of not more than 280 rat units or not more than 280 international units of chorionic gonadotropic homone in each 10 cc., and contained in each cubic centimeter an amount of anterior pituitary-like sex hormone having a physiological activity, if any, of not more than 28 rat units.

On April 22, 1943, the defendants having entered pleas of guilty, the court imposed fines of $100 against Benjamin W. Feldman, $300 against Murray Blaivas, and $500 each against Abraham J. Blaivas and Emanuel Mandelbaum. Sentences against each of the defendants of 6 months in prison were suspended and the defendants were placed on probation for 18 months.

922. Adulteration of Ladner's Improved Poultry Mixture. U. S. v. Ezra Everett Ladner (Ladner's Laboratories). Plea of guilty. Sentence, 6 months in Federal jail; sentence suspended and defendant placed on probation for 6 months. (F. D. C. No. 4138. Sample No. 35410–E.)

On July 18, 1942, the United States attorney for the Southern District of Alabama filed an information against Ezra Everett Ladner, trading as Ladner's Laboratories at Mobile, Ala., alleging shipment on or about January 3, 1941, from the State of Alabama into the State of Mississippi of a quantity of Ladner's Improved Poultry Mixture which was adulterated and misbranded.

Analysis of the article showed that it contained 68 percent of hydrated lime (calcium hydroxide), 11.96 percent of Epsom salt (magnesium sulfate), 7.68 percent iron hydroxide (equivalent to 5.74 percent iron oxide), 11.11 percent sulfur, and 1.95 percent acid-insoluble residue (which was chiefly sand and silica).

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, since it was represented in its labeling as consisting of the following ingredients in the stated proportions: "Magnesium Sulphate .062–3%, Sulphur Lotum .062–3%, Calcium Hydroxide .100%, Mineral Oxide of Iron .081%," whereas it did not consist of the ingredients in the proportions stated, but did consist essentially as disclosed by the analysis above.

The article was alleged to be misbranded in that the statements "Contents Magnesium Sulphate .062–3%, Sulphur Lotum .062–3%, Calcium Hydroxide .100%, Mineral Oxide of Iron .081%," borne on the carton, were false and misleading since the article did not consist of the ingredients in the stated proportions. It was alleged to be misbranded further in that statements on the carton regarding the efficacy of the article in the cure, mitigation, treatment, or prevention of disease in poultry were false and misleading, since they represented that the article would be efficacious in the treatment of cholera, roup, sorehead, white diarrhea, worms, and limber neck; that it would restore the health of baby chicks; that it would be beneficial in the breeding of fancy poultry, and would improve and maintain the health of the flock and thus increase egg production, whereas the article would not be efficacious for such purposes.

On January 18, 1943, the defendant having entered a plea of guilty, the court imposed a sentence of 6 months in the Federal jail in New Orleans, but suspended the sentence and placed him on probation for 6 months.

923. Adulteration and misbranding of aromatic spirit of ammonia, and sweet spirit of nitre. U. S. v. 18 Dozen Bottles of Aromatic Spirit of Ammonia and 18 Dozen Bottles of Sweet Spirit of Nitre. Default decree of condemnation and destruction. (F. D. C. No. 7518. Sample Nos. 87895–E, 87896–E.)

On May 23, 1942, the United States attorney for the Eastern District of North Carolina filed a libel against the above-named products at Littleton, N. C., alleging that the articles had been shipped in interstate commerce on or about March 21, 1942, by the Baker Drug Corporation, Norfolk, Va.; and charging that they were adulterated and misbranded.

Analysis of a sample of the aromatic spirit of ammonia showed that it contained not less than 2.95 grams of total ammonia in each 100 cc. and not more than 58.2 percent of alcohol, whereas the United States Pharmacopoeia provides, among other things, that each 100 cc. shall contain not more than 2.1 grams of total ammonia and that the alcohol content shall be between 62 and 68 percent by volume.

Examination of a sample of the sweet spirit of nitre showed that its specific gravity was 0.8347 at 25° C. and that its ethyl nitrite content was extremely variable, ranging from 0.77 percent to 2.09 percent, whereas the Pharmacopoeia provides, among other things, that the article shall contain a specific gravity of

not more than 0.823 at 25° C. and shall contain not less than 3 percent of ethyl nitrite.

The articles were alleged to be adulterated in that they purported to be drugs, the names of which are recognized in an official compendium, and their strength differed from the standards set forth in such compendium, and their difference in strength from such standards was not stated on their labels.

They were alleged to be misbranded in that the name and address of the manufacturer appeared in a very small size of type which, on some labels, was practically illegible and was therefore not prominently placed upon the labels with such conspicuousness, as compared with other words, statements, designs, or devices, as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

On August 14, 1942, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

924. Adulteration and misbranding of Azamine Capsules. U. S. v. 4 Boxes of Azamine Capsules. Default decree of condemnation. Product ordered destroyed. (F. D. C. No. 8018. Sample No. 7216–F.)

This product contained the active ingredient in excess of the amount declared on the label, and it would not be an effective treatment for various disease conditions for which it was recommended in the labeling.

On July 31, 1942, the United States attorney for the Eastern District of Wisconsin filed a libel at Milwaukee, Wis., against 4 boxes of Azamine Capsules, alleging that the article had been shipped in interstate commerce on or about June 8, 1942, by the Nepera Chemical Co., Inc., from Yonkers, N. Y.

Analysis of a sample of the article showed that each capsule contained not less than 5.89 grams (90.9 grains) of tolyl azo diamino pyridine hydrochloride.

It was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess.

It was alleged to be misbranded in that the statement "5 Grams * * * Each capsule contains 5 grams (77.2 grs. app.) of Tolyl-Azo-Diamino-Pyridine-Hydrochloride," borne on the label, was false and misleading.

The article was also alleged to be misbranded in that statements made in the labeling which represented and suggested that it was effective in the treatment of various disease conditions were false and misleading since it was not effective for these conditions. Some of the representations made were that Azamine has been shown to possess marked bactericidal power in coccal and *B. coli* infections, and that it was an antiseptic of proved value in a wide range of infections in large and small animals. It was recommended for mastitis, metritis, vesicular vaginitis, urinary infections, necrotic lesions, sinuses and fistulae, as well as for acute septic metritis, cystitis, nephritis, coccidiosis, gastritis, enteritis, septicemia and pyemia. It was also recommended as a topical application for udder and teat injuries, keratitis, conjunctivitis, and traumata of eye and associated tissues.

On October 1, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

925. Adulteration and misbranding of Paracelsus. U. S. v. 26 Boxes of Paracelsus. Default decree of condemnation. Product ordered destroyed. (F. D. C. No. 8161. Sample No. 4205–F.)

On or about August 23, 1942, the United States attorney for the Southern District of Indiana filed a libel at New Albany, Ind., against 26 boxes of Paracelsus at Bedford, Ind., alleging that the article had been shipped in interstate commerce on or about May 22, 1942, by the American Biochemical Corporation from Cleveland, Ohio.

The labeling of the article represented it to possess the following ingredients: Phosphorus, 245 milligrams; calcium, 84 milligrams; iron, 12 milligrams; iodine, 2.40 milligrams; manganese, .09 milligram; magnesium, 8 milligrams; and sulfur, 68 milligrams.

Analysis of the article showed that it was a mixture of chemical salts, principally sodium phosphate, potassium chloride, table salt, magnesium sulfate, calcium lactate, sodium bicarbonate, and lesser quantities of other chemical salts. The article was approximately 93 percent deficient in phosphorus, 55 percent deficient in calcium, 90 percent deficient in iron, and contained no iodine. It contained 211 percent more manganese, 181 percent more magnesium, and 63 percent more sulfur than was declared on the label.

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess.

It was also misbranded in that the statements with respect to the mineral content were false and misleading, since the statements were incorrect. It was further misbranded since statements made in the labeling representing and suggesting that the product was efficacious as a dietary supplement, as a body builder, as a tonic, and to correct disorders arising from dietary deficiencies, were false and misleading. The product was also recommended in the labeling as efficacious in the treatment of arthritis, rheumatism, neuritis, influenza, and phlebitis, and was represented as a combination of inorganic minerals in their most assimilable form, which would supply the minerals necessary to normal nutrition in the most desirable amounts. In fact, the article was not efficacious for the purposes recommended and was not a combination of inorganic minerals in their most assimilable form, which would supply the minerals necessary to normal nutrition in the most desirable amounts.

On October 9, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

926. Adulteration of Mennen Antiseptic Oil. U. S. v. 38 Packages of Mennen Antiseptic Oil. Default decree of condemnation. Product ordered delivered to New York City Salvage Committee. (F. D. C. No. 8250. Sample No. 16841–F.)

On August 27, 1942, the United States attorney for the Southern District of New York filed a libel against 38 packages of Mennen Antiseptic Oil at New York, N. Y., alleging that the article had been shipped in interstate commerce on or about February 16, 1942, by the Mennen Co., from Newark, N. J.

Bacteriological examination showed that the article was neither germicidal nor self-sterilizing. Chemical examination showed that it consisted of a yellow, perfumed, saponifiable oil containing small amounts of hydroxyquinoline, chlorobutanol, hydroquinone, and benzoic acid. The article was alleged to be adulterated in that its strength differed from that which it was represented to possess in the labeling, "Germicidal * * * Self Sterilizing."

It was alleged to be misbranded in that the following statements appearing in the labeling were false and misleading since the article was not a germicide, was not self-sterilizing, and was not efficacious for the symptoms and conditions mentioned: "* * * Germicidal * * * Self-Sterilizing * * * It is so medicated as to make the oil * * * germicidal * * * self-sterilizing. * * * It has equal antiseptic and germicidal powers to the commonly used ammoniated mercury ointments. * * * The oil is self-sterilizing, and autoclaving is not necessary. * * * It helps kill and prevent the growth of pyogenic organisms as long as it is in contact with the skin. * * * It helps maintain and conserve vital body temperature. It helps sterilize * * * the diaper area. * * * Meets the widespread demand of hospitals, physicians, nurses and mothers * * * germicidal * * * and self-sterilizing oil * * * offers protection against infection * * * Mennen Antiseptic Oil aids in keeping the skin of the babies free from pyogenic organisms. * * * quickly relieves * * * aggravated skin conditions. Prescribed where * * * germicidal oil dressing is required."

It was alleged to be misbranded further in that it was fabricated from two or more ingredients and its label failed to bear a statement of the quantity or proportion of chlorobutanol, a chloroform derivative, contained therein.

On October 1, 1942, no claimant having appeared, judgment of condemnation was entered and the court ordered the marshal to deliver the article to the New York City Salvage Committee for national defense and salvage purposes.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS [22]

DRUGS FOR HUMAN USE

927. Action to restrain and enjoin interstate shipment of Dolphin's Natural Barks. U. S. v. Byron J. Dolphin (Dolphin's Natural Barks). Tried to the court and jury. Verdict in favor of the Government. Permanent injunction granted. (Inj. No. 44.)

On December 5, 1942, the United States attorney for the Western District of Washington filed a complaint against Byron J. Dolphin, doing business as Dolphin's Natural Barks at Seattle, Wash., alleging that the defendant for many years past had been engaged in the sale and distribution of an article of drug

[22] See also Nos. 901–903, incl., 905–914, incl., 917–922, incl., 924–926, incl.

called Dolphin's Natural Barks, and that the article was made up in liquid form and sold and distributed by the defendant in small glass bottles enclosed in cardboard cartons.

The complaint alleged further that the article was misbranded in that certain statements appearing in its labeling were false and misleading. (The misbranding allegations in the complaint were sustained by the court's "Findings of Fact" and "Conclusions of Law" set forth hereinafter.)

The complaint alleged further that the defendant and his agents had been in the past and were then introducing and delivering the article for introduction into interstate commerce, and prayed that judgment and decree be entered permanently restraining and enjoining the defendant, his agents and employees, and all persons acting in concert with them, from continuing to do so, and prayed that a preliminary injunction be granted restraining the defendant during the pendency of the action. On the same date and pursuant to the motion of the United States attorney, an order was entered for the defendant to show cause why he, his agents, and employees should not be restrained and enjoined during the pendency of the action.

On December 14, 1942, the case having come on for hearing, the court orally ruled that the Government was entitled to the preliminary injunction on the ground that its evidence, showing the article had no curative value, was uncontroverted, and on December 16, 1942, a restraining order pendente lite was entered pursuant to such oral ruling.

The case came on for trial on March 7, 1944, at which time the court, upon its own motion impaneled an advisory jury. On March 9, 1944, evidence having been admitted on behalf of the parties and the cause submitted to such jury, a verdict was returned in favor of the Government, together with a special verdict finding that the product was misbranded. On March 20, 1944, the court having duly considered the matter, made the following findings of fact and conclusions of law:

BOWEN, *District Judge:*

FINDINGS OF FACT

I.

"That the defendant BYRON J. DOLPHIN is a resident of Seattle, Washington, and is doing business under the firm and trade name of Dolphin's Natural Barks.

II.

"That the defendant has been for some years past and is now engaged in the manufacture, sale and distribution of a product and article of drug called 'Dolphin's Natural Barks,' and that said product is made up in liquid form and is sold and distributed by the defendant in small glass bottles enclosed in cardboard cartons.

III.

"That there is attached and affixed to the said cartons and to the said bottles certain labels, and there is inserted in each carton a leaflet or circular, and that such labels and leaflet make certain statements and representations concerning said product, its constituents and the efficacy of said product as a treatment for diseases of the eye; that the leaflet contained in said carton constitutes a part of the labeling of said product.

IV.

"That the statements and representations appearing on the said labeling regarding the efficacy of said product in the cure, mitigation, treatment or prevention of diseases of the eye are false and misleading in that they falsely represent and suggest: That said drug contains natural barks; that drops of said drug when applied to the eyes are wonderful for diseases of the eye; that said drug is manufactured by a new process from tamarack bark, oak bark, and contains minerals from organic and inorganic sources, to-wit, aluminum, iron, manganese, calcium, magnesium, sodium and potassium; that the continued use of said drug will remove the sting from eyes which are in bad condition because of disease; that said drug will restore eyesight and prevent blindness; that said drug is efficacious and beneficial in the cure, mitigation, treatment and prevention of granulated eyelids and ulcers; that said drug has been efficacious and beneficial in the cure, mitigation, treatment and prevention of disease of the eye after

doctors have failed to give relief; that said drug is a miraculous and mysterious discovery revealed by Divine Providence.

V.

"That said drug does not constitute an appropriate or effective remedy for the purposes stated, recommended and suggested in said labeling; that said product and drug does not contain the ingredients it is represented to contain in said labeling; that the said product is essentially water.

VI.

"That the defendant has heretofore shipped the said product and drug with the aforesaid labeling accompanying it in interstate commerce from Seattle, Washington, to various parts of the United States.

"From the foregoing FINDINGS OF FACT, the Court makes the following:

CONCLUSIONS OF LAW

I.

"That the Court has jurisdiction of the parties to this action and of the subject matter thereof.

II.

"That the product 'Dolphin's Natural Barks' is a drug within the meaning and contemplation of the Federal Food, Drug and Cosmetic Act.

III.

"That the printed matter affixed to the bottle which contains said drug and to the carton in which said drug is packaged, and to the leaflet or circular inserted in said carton constitutes and is the labeling of said product within the meaning and contemplation of the Federal Food, Drug and Cosmetic Act.

IV.

"That the said product and drug 'Dolphin's Natural Barks' is misbranded within the meaning and contemplation of the Federal Food, Drug and Cosmetic Act.

V.

"That the defendant has heretofore violated the provisions of the Federal Food, Drug and Cosmetic Act, and that said defendant, his agents and employees and any and all persons acting in concert with said defendant or his agents or employees should be permanently restrained and enjoined from introducing or delivering for introduction in interstate commerce, or from in any manner aiding or assisting in the introduction or delivery for introduction into interstate commerce of the said product and drug 'Dolphin's Natural Barks.'

VI.

"That the plaintiff should recover judgment against the defendant for its costs herein incurred."

On the same date, March 20, 1944, a decree was entered granting a permanent injunction in accordance with the prayer of the complaint.

928. Alleged misbranding of Dolphin's Natural Barks. U. S. v. Byron J. Dolphin (Dolphin's Natural Barks). Plea of not guilty. Tried to a jury. Verdict of guilty. Motion for new trial granted and case subsequently dismissed. (F. D. C. No. 7243. Sample No. 11343-E.)

On July 16, 1942, the United States attorney for the Western District of Washington filed an information against Byron J. Dolphin, trading as Dolphin's Natural Barks, Seattle, Wash., alleging shipment on or about December 27, 1941, from the State of Washington into the State of Texas of a quantity of a drug, known as Dolphin's Natural Barks, which was misbranded.

Analysis of a sample of the article showed that it consisted essentially of water containing 0.0060 gram of solids per 100 cc.

It was alleged to be misbranded in that certain statements in its labeling which represented and suggested that it contained natural barks; that drops of the article, when applied to the eye, were wonderful for diseases of the eye; that it was manufactured by a new process from tamarack bark and oak bark,

and contained minerals from organic sources, that is aluminum, iron, manganese, calcium, magnesium, sodium, and potassium; that the continued use of the article would remove the sting from eyes which were in bad condition because of disease; that it would restore eyesight and prevent blindness; that it was efficacious in the cure, mitigation, treatment, or prevention of granulated lids and ulcers; that it was efficacious in the cure, mitigation, treatment or prevention of disease of the eye after doctors failed to give relief; that it was a mysterious and miraculous discovery revealed by Divine Providence; that it was a perfect eye medicine, the sole ingredients of which were natural barks; that it was a perfect, absolutely harmless eye medicine and would work miraculous cures of diseases of the eye were false and misleading since the drug was neither an article of the nature represented nor was it efficacious or wonderful for diseases of the eye as represented.

On October 29, 1942, the defendant having entered a plea of not guilty, the case come on for trial before a jury which, after deliberation, returned a verdict of guilty. Upon polling the jury, one member stated that he was not satisfied as to the defendant's guilt although he had so voted, and on this basis the court granted the defendant's motion for a new trial. On December 5, 1942, the case was dismissed. (See also notice of judgment No. 927 this issue.)

929. Misbranding of Tritolac, Alimentone Powder, and Alimentone Tablets. U. S. v. Thomas E. Collins (Thomas E. Collins Co.). Tried to the court. Defendant adjudged guilty and fined $200. (F. D. C. No. 6398. Sample Nos. 32623–E to 32626–E, incl.)

On February 27, 1942, the United States attorney for the Northern District of California filed an information against Thomas E. Collins, trading as Thomas E. Collins Co., at San Francisco, Calif., alleging shipment on or about July 15, 1940, from the State of California into the State of Arizona of quantities of the above-named drugs which were misbranded.

Analysis of a sample of the Tritolac showed that it consisted essentially of embryonic tissues closely resembling wheat germ, a spray-dried product closely resembling spray-dried skim milk, and an appreciable amount of wheat bran particles. It was alleged to be misbranded in that statements in the labeling which represented that it would be efficacious in the cure, mitigation, treatment, or prevention of disease were false and misleading since they represented and suggested that the article would be efficacious in restoring vitality and in maintaining resistance; that it was an excellent tonic for the nervous person and those in a run-down condition; that it would be efficacious in the correction of functional and degenerative changes in the entire nervous system and similar changes in the organs and tissues of the body; that it was efficacious in the treatment of acidosis and other digestive disturbances; that it was a wonderful rebuilder of those who were underweight due to malassimilation or wasting diseases, and would be efficacious in producing increased growth and increased weight in children, whereas the article would not be efficacious for such purposes.

Analysis of a sample of the Alimentone Powder showed that it consisted essentially of a spray-dried product, such as spray-dried skim milk, embryonic tissues, such as wheat germ, and dried green leafy or stemmy materials such as garden vegetables. Analysis of a sample of the Alimentone Tablets showed that they consisted essentially of embryonic tissues, such as wheat germ, and dried green leafy and stemmy material, such as garden vegetables. The Alimentone Powder and Tablets were alleged to be misbranded in that the statements regarding their efficacy in the cure, mitigation, treatment, or prevention of disease, appearing in the circular which accompanied them, were false and misleading in that they represented and suggested that the articles would be efficacious in the treatment of overweight; that they would be efficacious to expel mucus and to relieve colds, nasal catarrh, asthma, bronchitis, mucus colitis, and other catarrhal conditions; that they would be efficacious in the treatment of inflammation of the mucus membranes and of congested and infected tissues; that they would maintain the normal flow of secretions from the mucus membranes and thus continuously flush away any impurities which might lodge in the cell tissues; that they would maintain the defensive reaction against impurities and bacteria in the cell tissues and would increase the discharge from the part affected and eliminate accumulated waste; that they would be efficacious in the treatment of bronchial asthma and all types of catarrhal conditions including nasal catarrh, mucus colitis, and vaginal catarrh; that they would keep the membranes in a healthy condition, and would be efficacious in the treatment of hay fever; and that they would heal inflammation and tone

the membranes, and would eliminate toxic deposits from the tissues, whereas they would not be efficacious for such purposes.

On April 28, 1943, the defendant having entered a plea of not guilty and a jury having been waived, the case came on for trial before the court. During the course of the trial the information was amended in order to strike the circular alleged to have accompanied the Alimentone Powder and Tablets, and to substitute a different circular. No amendment, however, was made to the charges based on the stricken circular hereinbefore set forth. The case was concluded on April 30, 1943, with a finding of guilt by the court. A fine of $200 was imposed.

930. Misbranding of Tonico Fir-Veta. U. S. v. Geneovevo Gonzales Garcia (El Modelo Medicine Co.) Plea of guilty. Fine, $25. (F. D. C. No. 6416. Sample No. 7617–E.)

On December 22, 1942, the United States attorney for the Western District of Texas filed an information against Genevevo Gonzales Garcia, trading as El Modelo Medicine Co., at San Antonio, Tex., alleging shipment on or about November 25, 1940, from the State of Texas into the State of California of a quantitiy of Tonico Fir-Veta which was misbranded.

Analysis of a sample of the article showed that it consisted essentially of strychnine and quinine salts, small portions of iron, calcium, manganese and potassium compounds including hypophosphites, alcohol, and syrup.

The article was alleged to be misbranded in that certain statements appearing in the circular accompanying the article were false and misleading since they represented and suggested that the article would promote, restore, and insure health; that it would be efficacious to increase resistance in children, relieve them of over-tension, strengthen their bones and enable them to gain weight and sleep more restfully, and would correct the causes of nervousness, poor health and lack of energy in children; that it would be efficacious to stimulate the appetite and give additional energy and would keep working girls physically fit, give them a good appetite, and increase their vitality; that it would maintain a high body resistance and ward off colds, croup, and other infections, and would be efficacious in the treatment of tired, nervous, disordered stomach and sluggish bowels, whereas the article would not be efficacious for such purposes.

It was alleged to be misbranded further in that the statements: "El Modelo Medicine Co. has complied with the new Federal Food, Drug and Cosmetic Act," and "The laws regulating the manufacture and sale of Drugs and Medicines for your protection, the new Federal Food, Drug, and Cosmetic Act, have been fully complied with by 'El Modelo Medicine Co.'," appearing in the circular, were false and misleading since they implied that the article complied with the Federal Food, Drug, and Cosmetic Act, whereas it did not comply with such Act.

It was alleged to be misbranded further in that its container, a carton, was so made, formed, and filled as to be misleading, since the carton was much larger than was necessary to hold the bottle contained in it.

On January 22, 1943, the defendant having entered a plea of guilty, the court imposed a fine of $25.

931. Misbranding of Tuberculosis Compound. U. S. v. Emile Carpentier (Dr. Emile Carpentier, N. D.) Tried to court and jury. Verdict of guilty. Sentence, 1 year's imprisonment. Sentence suspended and defendant placed on probation for 5 years. (F. D. C. No. 7193. Sample No. 51921–E.)

On July 17, 1942, the United States attorney for the District of New Jersey filed an information against Emile Carpentier, trading as Dr. Emile Carpentier, N. D., at Hillsdale, N. J., alleging shipment on or about October 1, 1941, from the State of New Jersey into the State of Massachusetts of a quantity of a drug, described in the label as "Tuberculosis Compound," which was misbranded.

Analysis of a sample of the article showed that it consisted essentially of plant material, sugars, a fatty substance, and water.

The article was alleged to be misbranded in that the statements in the labeling which represented and suggested that it would cure, in from 6 weeks to 6 months time, tuberculosis of the lungs, the larynx, the bones, the intestines, the kidneys, and the brain, that it would be efficacious in the cure, mitigation, treatment, or prevention of chronic bronchitis, congested lungs, colitis, chronic gastritis, ulcerated duodenum, ulcerated stomach, and ulcerated intestines; that it contained tested exhilarating and vitalizing herbs, roots, and ingredients which would eliminate the germs ("bugs") of tuberculosis, were false and misleading, since the article would not be efficacious for such purposes.

On April 7, 1943, the case came on for trial before the court and a jury. The trial was concluded on April 8, 1943, and the jury returned a verdict of guilty. The court imposed a sentence of 1 year in the custody of the Attorney General, but suspended the sentence and placed the defendant on probation for 5 years.

932. Misbranding of "SNL." U. S. v. Mrs. Cora Lee Wiley (The SNL Co.) Plea of nolo contendere. Defendant placed on probation for 5 years. (F. D. C. No. 7247. Sample Nos. 944–E, 37930–E, 48065–E, 69586–E.)

The labeling of this product contained false and misleading therapeutic claims and did not bear an accurate statement of the quantity of the contents in terms of measure, or a statement of the quantity or proportion of the alcohol in the product.

On June 5, 1942, the United States attorney for the Middle District of Georgia filed an information against Mrs. Cora Lee Wiley, trading as the SNL Co., Adel, Ga., alleging shipment on or about May 27 and July 19, 1941, from the State of Georgia into the States of Florida and New Jersey of quantities of "SNL" which was misbranded. Portions of the article were labeled in part: (Bottle) "SNL (Suffer No Longer)."

Analysis of samples of this drug showed that it consisted essentially of iodine, boric acid, organic silver compound, iodide, sulfate, a small amount of magnesium compound, alcohol, glycerine, and water.

The drug was alleged to be misbranded in that it was in package form and its label failed to bear an accurate statement of the quantity of the contents in terms of measure; and in that it was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients and its label failed to bear a statement of the quantity or proportion of alcohol contained in the drug.

One shipment of the article was alleged to be misbranded further in that certain statements appearing in the labeling which represented and suggested that the article would end suffering; that it would be an effective relief for female trouble, soreness in the abdomen, and aching hips; that, when used with the positions described in the statements, it would aid in replacing the female organs and would relieve strained sore muscles, and that it would be effective as a dressing for the tenderest old sores and such were false and misleading since it would not be efficacious for such purposes.

The remaining shipments were alleged to be misbranded further in that certain representations in the labeling that the article would end suffering; that it was an effective relief for female trouble, soreness in the abdomen and aching hips; that it would prevent the aging process in the individual; that it would be effective in the treatment of infected female organs, nervousness, muddy, sallow complexions, aching head, hips, limbs, and other aches and pains; that it would be effective in the cure, mitigation, treatment, or prevention of a weakened condition due to female trouble; that it would protect women against every germ including tuberculosis, and would enable the user to overcome despondency, worry, poverty, half-aliveness, apathy, lethargy, resignation, and hopelessness; that it would enable the user to build health, happiness, strength, beauty, and to increase the length of life; that it would penetrate sore, congested organs at once; would relieve discharge or painful menses; that it would condition the female organs while in change of life; and that when used with the positions described in the labeling, it would relieve bearing-down pains, sore muscles, and would replace fallen wombs; and in that certain additional representations in the labeling of two of such shipments that the drug would aid in replacing the female organs and would relieve strained, sore muscles and that it would be effective as a dressing for the tenderest old sores and such were false and misleading since the drug would not be efficacious for such purposes.

On March 16, 1943, the defendant having entered a plea of nolo contendere, the court placed the defendant on probation for 5 years, conditioned that she should not deal in the above-named drug except with the consent of the Food and Drug Administration.

933. Misbranding of coconut milk and powdered milk of soya bean. U. S. v. John Bruno Radcliffe (Radcliffe Soya Products). Plea of guilty. Defendant placed on probation. (F. D. C. No. 7260. Sample Nos. 13603–E, 13800–E, 21643–E, 21644–E, 63220–E.)

On August 11, 1942, the United States attorney for the Northern District of California filed an information against John Bruno Radcliffe, trading as Radcliffe Soya Products, San Francisco, Calif., alleging shipment within the period from

on or about February 8, 1940, to November 24, 1941, from the State of California into the States of Idaho and Washington of a quantity of drug which was misbranded. The articles were labeled in part: (Cans) "Radcliffe's Original Powdered Milk of Soya Bean," or "Tropical Coconut Milk."

The powdered milk of soya bean was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it was endorsed by the U. S. Department of Agriculture, Washington, D. C.; that it was original powdered milk of soya bean, was especially valuable for infant feeding, and was as good as or better than mother's milk; that it was rich in vitamins; that it was a nerve, brain, and gland rejuvenator, and would be efficacious in the cure, mitigation, treatment or prevention of diabetes were false and misleading since the article was not endorsed by the U. S. Department of Agriculture, Washington, D. C.; it was not original powdered milk of soya bean; it was not especially valuable for infant feeding; it was not as good as or better than mother's milk, and was not rich in vitamins; it was not a nerve, brain, or gland rejuvenator, and would not be efficacious in the cure, mitigation, treatment, or prevention of diabetes.

The coconut milk was alleged to be misbranded in that the statements appearing in its labeling, which represented and suggested that it was a tropical coconut milk; that it would provide energy, strength, and vitality to the user; that it was efficacious for health building, and would be efficacious in the cure, mitigation, treatment, or prevention of colitis, underweight, weak stomach, stomach ulcers, nerve exhaustion and sleeplessness, and in the treatment of convalescents; and that it was rich in vitamins and minerals were false and misleading since the article was not a tropical coconut milk and would not provide energy, strength, or vitality to the user; it was not efficacious for health building, and would not be efficacious in the cure, mitigation, treatment, or prevention of colitis, or underweight, or weak stomach, stomach ulcers, nerve exhaustion or sleeplessness, nor in the treatment of convalescents; and it was not rich in vitamins or minerals.

The articles were also alleged to be misbranded under the provisions of law applicable to foods as reported in the notices of judgment on foods.

On November 3, 1942, the defendant having entered a plea of guilty, the court placed him on probation for 2 years.

934. Misbranding of Cruez Herb Douche and Cruez No. 9 and No. 10 Herb Tea. U. S. v. William H. Cruez, Sr. (St. Clair Herb Co.). Plea of guilty. Sentence suspended and defendant place on probation for 5 years. (F. D. C. No. 7314. Sample Nos. 1968–F, 7061–F to 7063–F, incl.)

The labeling of these products contained false and misleading therapeutic claims.

On April 24, 1943, the United States Attorney for the Eastern District of Illinois filed an information against William H. Cruez, Sr., a partner in the firm of St. Clair Herb Co., East St. Louis, Ill., alleging shipment on or about October 17, 19, and 24, 1942, from the State of Illinois into the States of Indiana and Missouri of quantities of the above-named drugs which were misbranded.

Analysis of the Cruez No. 10 Herb Tea showed that it consisted essentially of small proportions of extracts of plant drugs, salicylic acid, and water. It was alleged to be misbranded in that the statements, "Remedies that Build Health * * * Blood, Kidneys, Bladder, Rheumatism and Female Disorders," appearing in its labeling, represented and suggested that it would be efficacious to build health; that it would be efficacious in the cure, mitigation, treatment, or prevention of disorders and diseases of the blood, kidneys, and bladder, and of rheumatism and female disorders, and were false and misleading since it would not be efficacious for such purposes.

Analysis of the Cruez Herb Douche showed that it consisted essentially of a small proportion of ferric sulfate and smaller proportions of compounds of magnesium and calcium, and plant extractives and water. It was alleged to be misbranded in that the statements "Remedies that Build Health * * * Recommended in the Relief of Infections and Growths of the Female Organs," appearing in its labeling, represented and suggested that it would be efficacious to build health, and would be efficacious in the cure, mitigation, treatment, or prevention of infections and growths of the female organs, and were false and misleading since it would not be efficacious for such purposes.

Analysis of Cruez No. 9 Herb Tea showed that it consisted essentially of small proportions of extracts of plant drugs, salicylic acid, and water. It was alleged to be misbranded in that the statements "Remedies that Build Health * * *

Blood, Gout, Kidneys, Bladder, Rheumatism and Run Down Manhood," appearing in its labeling, represented and suggested that it would be efficacious to build health, and would be efficacious in the cure, mitigation, treatment, or prevention of disorders and diseases of the blood, kidneys, and bladder, and gout, rheumatism, and run-down manhood, that is, impaired sexual vigor, and were false and misleading since it would not be efficacious for such purposes.

All three of these products were also alleged to be misbranded further in that they were in package form and did not bear labels containing accurate statements of the quantity of their contents in terms of measure.

On June 17, 1943, the defendant having entered a plea of guilty, the court suspended imposition of sentence and placed the defendant on probation for 5 years, with provision that he should discontinue the sale or the giving away of medicines.

935. Adulteration and misbranding of Domino Brand Antiseptic Rubbing Compound with Isoprophyl Alcohol. U. S. v. 4,495 Dozen and 301 Dozen Bottles of Domino Brand Antiseptic Rubbing Compound with Isoprophyl Alcohol. Consent decree of condemnation. Product and labels ordered destroyed. Empty bottles returned to claimant. (F. D. C. No. 6124, 6216. Sample Nos. 75757–E, 75775–E, 75776–E.)

This product was short-volume and was neither antiseptic nor a rubbing alcohol. In addition, its label failed to bear a statement of the quantity of proportion of isopropyl alcohol present.

On November 1 and 15, 1941, the United States attorney for the District of Massachusetts filed libels at Boston, Mass., against 4,495 dozen bottles of Domino Brand Antiseptic Rubbing Compound with Isoprophyl Alcohol, alleging that the article had been shipped by Halitosine Co., St. Louis, Mo., from on or about September 19 to October 9, 1941, and against 301 dozen bottles of the same product shipped by Frank's Economy Store, Burlington, Vt., from on or about October 7 to 14, 1941.

Examination of samples taken from these consignments showed that the article consisted essentially of water, isopropyl alcohol approximately 9 percent by volume, methyl salicylate, boric acid, and menthol. The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess since it was not antiseptic, as stated in the labeling. It was alleged to be misbranded: (1) In that the statement "1 Pint" appearing on the label was false and misleading as applied to an article that contained less than 1 pint. (2) In that the word "Antiseptic" appearing on the label was false and misleading as the article was not antiseptic. (3) In that the following statements appearing on the label created the false and misleading impression that the article was rubbing alcohol or the equivalent of rubbing alcohol: "Rubbing Compound with Isoprophyl Alcohol * * * Used for Massaging, Sponging, After Bathing, Cooling and Refreshing for Hospital and Home." And (4) in that the label did not bear a statement of the quantity or proportion of isopropyl alcohol present. One lot, 301 dozen bottles, was alleged to be misbranded further in that the label did not bear a statement of the common or usual name of the drug since the word "Hexahydrothymol," borne on the label, is not the common or usual name of the ingredient menthol.

On December 18, 1942, Harry Lepler, trading as Lepler & Company, Boston, Mass., the claimant, having admitted the allegations of the libel, a consolidated decree of condemnation was entered and the court ordered that the contents of the bottles and their labels be destroyed, and the empty bottles be returned to the claimant.

936. Misbranding of aspirin tablets. U. S. v. 28 Dozen Packages of Aspirin Tablets. Default decree of condemnation. Product ordered distributed to charitable institutions. (F. D. C. No. 7517. Sample No. 83804–E.)

On May 16, 1942, the United States attorney for the Southern District of Texas filed a libel against 28 dozen packages of aspirin tablets at Houston, Tex., alleging that the article had been shipped in interstate commerce on or about January 29, 1941, by the Halitosine Co. from St. Louis, Mo.; and charging that it was misbranded in that the statement on the label, "100 Tablets," was false and misleading as applied to an article that was short-count, since the bottles did not contain 100 tables. The article was labeled in part: "Domino 100 Tablets Aspirin USP 5 Grains Each."

On July 21, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered distributed to a charitable institution.

937. Misbranding of Betene. U. S. v. 79 Packages of Betene. Default decree of condemnation and destruction. (F. D. C. No. 10050. Sample No. 8127–F.)

Examination of this product indicated that it was essentially a mixture of powdered skim milk, dried egg yolk, saccharin, cereal products, flavors, and combined calcium and phosphorus.

On June 5, 1943, the United States attorney for the District of Minnesota filed a libel against 79 packages of Betene at Faribault, Minn., alleging that the article had been shipped in interstate commerce on or about March 3 and 26, 1943, by the Vegetable Juice & Products Co. from Rochester, N. Y.; and charging that it was misbranded. The article was labeled in part: "Betene * * * A Special Dietary Supplement * * * L. H. Steward Corporation Rochester, New York."

The article was alleged to be misbranded in that the statements appearing on the label and in the circular entitled "Ive Found the Sure Way to Acquire Normal Weight," which accompanied the article in interstate commerce, were false and misleading since they represented and suggested and created in the mind of the reader the impression that the article, when consumed as directed, would cause an increase in weight and add to the vigor and vitality of the user; and also that when consumed as directed, it constituted a sure, sane, safe and effective way to reduce, whereas it would not accomplish such results.

The article was also alleged to be misbranded under the provisions of the laws applicable to foods, reported in food notices of judgment.

On July 27, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

938. Misbranding of Chagnon's Sirotar. U. S. v. 131 Bottles of Chagnon's Sirotar. Consent decree of condemnation. Product ordered released under bond for relabeling. (F. D. C. No. 7858. Sample No. 90894–E.)

On July 13, 1942, the United States attorney for the District of Rhode Island filed a libel against 131 bottles of Chagnon's Sirotar at Arctic (West Warwick), R. I., alleging that the article had been shipped in interstate commerce on or about May 1, 1942, from Worcester, Mass., by Brewer & Co., Inc.; and charging that it was misbranded. The label of the article bore a conspicuous pictorial design of a cod fish.

Examination of the article failed to reveal the presence of cod liver oil concentrate.

The article was alleged to be misbranded in that the statement "Cod Liver Oil Concentrate," and the pictorial design of a cod fish borne on the label were false and misleading as applied to an article which contained an inconsequential amount, if any, of cod-liver oil concentrate as one of its ingredients. It was alleged to be misbranded further in that its container was so made and filled as to be misleading since the carton containing the bottle was excessively large.

On December 23, 1942, Chagnon's Family Drug Store, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond, conditioned that it be relabeled.

939. Misbranding of Effervescent Kruschen. U. S. v. 17–5/6 Dozen Packages of Effervescent Kruschen. Decree of condemnation and destruction. (F. D. C. No. 6637. Sample No. 64647–E.)

Analysis showed that this product consisted essentially of 18.7 percent anhydrous Epsom salt (magnesium sulfate) with small proportions of common salt (sodium chloride), potassium chloride, sodium sulfate, and potassium sulfate, with an effervescent base consisting of a mixture of sodium bicarbonate and citric acid.

On January 3, 1942, the United States attorney for the Western District of Pennsylvania filed a libel against 17 5/6 dozen packages of Effervescent Kruschen at Pittsburgh, Pa., alleging that the article had been shipped on or about August 22, 1941, from Rochester, N. Y., by E. Griffiths Hughes, Inc.; and charging that it was misbranded in that the following statements appearing in the circular accompanying the article were false and misleading since they created the impression that the article constituted an effective agent for reducing weight, whereas it did not constitute an effective agent for such purpose: "As an Assistant To Diet In Reducing Fat Kruschen Salts thru a wholesome stimulating effect on the liver and bowels, and a mild diuretic effect on the kidneys offers assistance to sensible eating in the problem of overweight. This has similarities to the European Spa treatment for weight reduction and in a measure brings the so-called Spa treatment (sensible eating and mineral waters)

into the home without that extraordinary expense which accompanies visits to such resorts."

On May 4, 1942, E. Griffiths Hughes, Inc., claimant, having submitted a petition for salvage, requesting the release of the product, an order was entered that the product be released under bond for removal of the circular complained of and for labeling in accordance with the requirements of the law, under the supervision of the Food and Drug Administration. On August 3, 1943, the claimant having consented to the vacating of the order and having stated that it did not intend to defend, such order was cancelled and judgment of condemnation was entered, together with an order for the destruction of the product.

940. Misbranding of Eopa Home Remedies. U .S. v. 23 Packages of Eopa Home Remedies No. 75, 3 Packages of Eopa Tablets No. 58, 5 Packages of Eopa Home Remedies No. 234, and 2 Packages of Eopa Home Remedies No. 234. Default decree of condemnation. Products ordered destroyed. (F. D. C. Nos. 7367 to 7370, incl. Sample Nos. 93402–E to 93405–E, incl.)

On April 23, 1942, the United States attorney for the Western District of Washington filed a libel against the above-named products at Seattle, Wash., alleging that the article had been shipped into interstate commerce on or about January 13, 1941, and January 2 and February 10, 1942, by the Eopa Company from San Francisco, Calif.

Analysis of a sample of Eopa Home Remedies No. 75 showed that the article consisted essentially of milk sugar and starch with small amounts of talc, magnesium, and potassium phosphates. The article was alleged to be misbranded in that the statements appearing the labeling were false and misleading since they represented and suggested that it was efficacious in the treatment of neuritis, neuralgia and sciatica, whereas the article was not so effective. It was alleged to be misbranded further in that the label failed to bear the common or usual name of the active ingredients.

Examination of a sample of Eopa Tablets No. 58 showed that the article consisted essentially of milk sugar, starch, and sugar, with small amounts of plant material. The article was alleged to be misbranded in that certain statements appearing on the labeling which represented and suggested that it was efficacious in the treatment of grip, infectious colds, head colds, tickling coughs due to colds, hoarseness, spasmodic croup, coryza, and acute rhinitis, were false and misleading, since the article was not so effective.

Analysis of a sample of the Eopa Home Remedies No. 234 showed that it consisted essentially of milk sugar, starch, and sugar, with small amounts of lithium and ammonium compounds including phosphates. The product was alleged to be misbranded in that certain statements appearing on the labeling represented and suggested that it was efficacious in the treatment of arthritic rheumatism (inflamed joints), severe pain, arthritis, chronic rheumatism, and rheumatic gout, whereas the article was not so effective. Another lot of the same product was alleged to be misbranded in that its labeling bore statements that it was efficacious in the treatment of arthritis, stiff, aching joints, swollen, gouty, inflamed and deformed joints, arthritis, chronic rheumatism, and rheumatic gout, whereas the article was not so effective. It was alleged to be misbranded further in that the label failed to bear the common or usual name of the active ingredients of the product.

On October 30, 1942, no claimant having appeared, a decree of condemnation was entered and the court ordered the products destroyed.

941. Misbranding of first aid kit. U. S. v. 18 Dozen Packages of White Cross Emergency First Aid Kit. Default decree of condemnation. Product ordered destroyed. (F. D. C. No. 7826. Sample No. 66260–E.)

On July 2, 1942, the United States attorney for the Northern District of Illinois filed a libel at Chicago, Ill., against 18 dozen packages of White Cross Emergency First Aid Kit, alleging shipment in interstate commerce on or about May 8, 1942, by the American White Cross Laboratories, Inc., from New Rochelle, N. Y.

Examination of samples taken from this consignment showed that the adhesive bandages in the kits were not sterile, but were contaminated with living spore-bearing bacilli and cocci.

The article was alleged to be misbranded in that the statements, "Emergency First Aid Kit" and "Be Prepared," which appeared on the can, were false and misleading for the following reasons: The adhesive was not sterile, but was contaminated with living micro-organisms and was not suitable for first aid purposes; it was not a first aid kit since it did not contain material for treating

any condition except minor cuts and abrasions, and the article was solely a kit for minor cuts and abrasions.

On October 27, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

942. Misbranding of Presto for Blackheads. U. S. v. 11 Packages of Presto for Blackheads. Default decree of condemnation. Product ordered destroyed. (F. D. C. No. 8100. Sample No. 12815–F.)

On August 14, 1942, the United States attorney for the District of Oregon filed a libel at Portland, Oreg., against 11 packages, each containing 1 dozen sticks, of an article labeled, "Presto for Blackheads," alleging that the article had been shipped in interstate commerce on or about July 21, 1942, by the McJohn Cosmetic Co. from Hollywood, Calif.

Analysis of a sample of the product showed that it consisted essentially of a mixture of ground pumice and titanium dioxide, incorporated in a hydrated waxy base.

The article was alleged to be misbranded in that the following statements appearing in the labeling were false and misleading as applied to a product that was not effective in removing blackheads and in keeping the pores of the skin clean: "Presto for Blackheads. Quick Aid for Blackheads * * * A clean skin is the foundation for a beautiful complexion: don't allow your complexion to be marred by unsightly Blackheads. Never squeeze or pinch Blackheads; squeezing injures the skin and encourages large pores and Blackheads. Use Presto Stick and Eliminate Squeezing * * * In case of stubborn Blackheads use Presto Stick once daily for several days. Thereafter use from time to time, as required, to keep the pores clean."

It was alleged to be misbranded further in that the label failed to bear the common or usual name of the active ingredients.

The article was also misbranded as reported in cosmetic notices of judgment.

On October 8, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

943. Misbranding of Rel-Ka-Sol. U. S. v. 23 Packages of Rel-Ka-Sol. Default decree of condemnation. Product ordered destroyed. (F. D. C. No. 8240. Sample No. 1812–F.)

On August 31, 1942, the United States attorney for the Northern District of Indiana filed a libel at South Bend, Ind., against 23 packages of Rel-Ka-Sol. The article had been consigned in interstate commerce on or about May 27, 1942, by the Rel-Ka-Sol Chemical Co. from Philadelphia, Pa.

Analysis of a sample showed that the article consisted essentially of water, alcohol, and boric acid, together with small quantities of phenol and chlorthymol. Bacteriological examination showed that the article was not an antiseptic when diluted with two parts of water.

The article was alleged to be misbranded in that the following statements appearing in the labeling were false and misleading since it was not an antiseptic in the dilution recommended and was not effective in the treatment of the conditions represented: (Label) "To Prevent and Treat Infection * * * diluted with two parts water. Kill germs * * * For Sore Throat," (carton) "To Prevent and treat infection * * * Abscess or Boils * * * Tonsilitis * * * Sore Throat * * * Sore and Infected Gums, Abscessed Teeth * * * Ear Discharge * * * Scalp Infection and All Diseases of the Scalp Infection of Any Kind," (circular) "An Antiseptic Solution * * * diluted with two parts water * * * Abscess or Stye of the Eye * * * Treat all infections immediately with Rel-Ka-Sol * * * It kills germs (even when diluted). * * * A large bottle when diluted with two parts of water makes more than a quart of effective mouth-wash."

On October 1, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

944. Misbranding of Formula S–12 Vitamins-Minerals. U. S. v. 30 Dozen Bottles of Formula S–12 Vitamins-Minerals. Default decree of condemnation and destruction. F. D. C. No. 9393. Sample No. 32614–F.)

On February 24, 1943, the United States attorney for the Southern District of Indiana filed a libel against 30 dozen bottles of the above-described product at Indianapolis, Ind., alleging that the article had been shipped in interstate commerce within the period from on or about January 10 to 14, 1943, by the Universal Products Co. from Cleveland, Ohio; and charging that it was misbranded. The

article was labeled in part: "Formula 8–12 Vitamins—Minerals Contains Soy Bean Meal, Wheat Embryo, Gum Karaya, Brewer's Yeast, Kaolin, Kelp, Activated Ergosterol, Natural Vitamin A Ester, Thiamin Hydrochloride, Riboflavin, Dicalcium Phosphate, Iron Bihydrogen, Potassium Iodide and Oil of Orange."

The article was alleged to be misbranded in that statements which appeared on the label which represented and suggested that the article was of significant nutritional value by reason of the presence therein of Vitamin E, Vitamin B_{12}, and other factors of the B complex as found in brewer's yeast and the elements, potassium, sulfur, sodium, magnesium, copper, zinc, chlorine, and manganese were false and misleading since the product was not of significant value by reason of the presence therein of such vitamin factors and elements.

It was alleged to be misbranded further in that representations in the labeling that consumption of the product would insure normal functioning of the brain, eye, pituitary gland, parathyroid gland, thymus, heart, liver, and gall bladder, stomach and digestive system, gastro-intestinal tract, pancreas, suprarenals and adrenals, kidneys, bladder, gonads, prostate, nerves, arteries, veins, lymphatics (blood and blood vessels), muscles, bones, and joints, ligaments, tendons, and marrow, pineal gland, the ear, eye, spinal cord, spleen, hair, skin, complexion, teeth and gums, thymus, lungs, mammary gland, reproductive system (ovary, placenta, prostate-gonads, etc), and the nails, and that the article would be efficacious in the treatment or preventions of colds, infections of the lungs, formation of kidney stones and infections, the formation of bladder stones, cystitis, and other bladder infections, muscular spasms, cramps, exhaustion, inflammation, and paralysis, ulcer of the eye, conjunctivits, cataracts, and night blindness, scaliness, dryness, paleness of the skin and various skin sores, gum infections, scurvy, and loose teeth, and would be efficacious to promote health, and cause the hair to be glossy and healthy were false and misleading since consumption of the article would not insure normal functioning of the various organs of the body as represented and would not be efficacious in the treatment or prevention of the various disease conditions mentioned and suggested.

The article was also alleged to be misbranded under the provisions of the law applicable to foods reported in food notices of judgment.

On April 22, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

945. Misbranding of Vita Malt with Natura Calcium Compound. U. S. v. 51 Combination Packages of Vita Malt with Natura Calcium Compound. Default decree of condemnation and destruction. (F. D. C. No. 5226. Sample No. 60296–E.)

These articles were represented as being effective in reducing body weight and as valuable in the treatment of a wide variety of pathological conditions.

On July 30, 1941, the United States attorney for the Western District of Washington filed a libel against 51 combination packages of Vita Malt with Natura Calcium Compound, alleging shipment on or about May 23, 1941, from Los Angeles, Calif., to Olympia, Wash., by the Natura Remedy Co., Los Angeles, Calif. In each combination package were articles labeled in part: (Bottle) "Vita Malt Contains Vitamins," (package) "Natura Calcium Compound," (circular) "Do you know that Vitamins Build Health," and (leaflet) "Now You can Reduce Safely."

Analysis of a sample of Vita Malt showed that it was essentially a malt extract, with small amounts of saponifiable oils, water, and sodium benzoate.

It was alleged to be misbranded in that the statements on the label representing and suggesting that it would be effective in reducing body weight were false and misleading, since it was not effective for this purpose. It was alleged to be misbranded further in that the statements in the labeling representing and suggesting that it would be of value in the treatment of a variety of pathological conditions such as anemia, nervousness, sleeplessness, glandular disturbances, lack of appetite, infections, rheumatism, neuritis, and arthritis were false and misleading since it would be of no value in the treatment of such pathological conditions.

Analysis of a sample of "Natura Calcium Compound" showed that it was a mixture of sodium bicarbonate and calcium salts.

The article was alleged to be misbranded in that it was offered as effective in the treatment of colds and grip, whereas it would not be effective for this purpose.

The Vita Malt was also alleged to be misbranded under the provisions of the law applicable to food, as reported in food notices of judgment.

On December 1, 1941, the Natura Remedy Co. having intervened and petitioned for removal of the case, the court entered an order removing it to the Southern

District of California. The Government thereupon filed a motion to remand the case to the Western District of Washington on the ground that the parties had stipulated for transfer to the Northern District of California and that the Southern District of California had no jurisdiction. On March 24, 1942, the Government's motion to remand the case was denied by the court without opinion. On October 13, 1942, the petition of intervention and answer of the Natura Remedy Co. having been withdrawn, a default judgment of condemnation was entered and the product was ordered destroyed.

946. Misbranding of Vitaminerals. U. S. v. 6 Bottles of Vitaminerals VM No. 1, et al. Default decree of condemnation and destruction. (F. D. C. Nos. 7938, 7939, 7941, 7942. Sample Nos. 81451–E, 81452–E, 81454–E to 81456–E, incl.)

On July 29, 1942, the United States attorney for the District of Colorado filed a libel at Denver, Colo., against 6 bottles of Vitaminerals VM No. 1, 7 boxes of Vitaminerals VM No. 1+, 8 bottles of Vitaminerals VM No. 100, and 35 bottles of Vitaminerals VM No. 120. A part of one of the shipments consisted of some booklets entitled "Vitamineral Therapy" and some cards entitled "Therapy Chart Doctors' Reference Chart." The article had been consigned in interstate commerce within the period from on or about May 5 to 27, 1942, by Vitaminerals Co. from Los Angeles, Calif.

Examination of a sample of Vitaminerals VM No. 1 showed that the article consisted mainly of rhubarb root with smaller proportions of other plant materials, including Irish moss, okra, cranberry fruit, and parsley leaf. The tablets, including coating, weighed 0.7 gram each, of which 0.2 gram was mineral matter. The article was alleged to be misbranded in that the statements in the booklet entitled "Vitamineral Therapy" and upon the card entitled "Therapy Chart Doctors' Reference Chart," relating to the article, were false and misleading since they represented and suggested that the preparation was essentially a vitamin constipation tablet or a vitamin-mineral laxative, and was a dietary supplement and a food. In fact, the preparation was not a vitamin constipation tablet or a vitamin-mineral laxative but was essentially a rhubarb laxative, and was not a dietary supplement or food. It was alleged to be misbranded further in that it was represented and suggested as a primary or secondary supplement in cases of arthritis due to excess calcium, arthritis due to systemic origins, colds, hemorrhoids, neuralgia, neurosis, obesity, and tonsilitis, whereas it would not be effective for any of these conditions.

Examination of a sample of Vitaminerals VM No. 1+ showed that the article consisted essentially of plant materials including rhubarb root, cascara sagrada, Podophyllum, Irish moss, cranberry fruit, parsley leaf, okra, a pungent drug such as cayenne pepper, and traces of peanut hull, and seed coat tissues. The article was alleged to be misbranded in that the statements appearing in the booklet and the card referred to above concerning this article were false and misleading since they represented and suggested that it was a vitamin laxative, or a vitamin-mineral laxative, and a dietary supplement, whereas it was essentially a rhubarb, cascara, and Podophyllum laxative, and was not a dietary supplement. It was alleged to be misbranded further in that it was offered as a primary or secondary supplement in the treatment of cases of colds, intestinal cramps, hemorrhoids, systemic hypertension, biliary stasis, engorgement of the liver, jaundice, malaria, neuralgia, neurosis, obesity, and tonsilitis, whereas it would not be efficacious for these purposes.

Examination of a sample of Vitaminerals VM No. 100 showed that the article was a vaginal suppository consisting of gelatin capsules contining mineral matter, principally iron sulfate and aluminum sulfate with a small fraction of 1 percent of a phosphate. The article was alleged to be misbranded in that the statement appearing on the label, "containing ferric sulfate, ferrous sulfate, and ferric phosphate" was false and misleading since the article did not contain any ferrous sulfate or any ferric sulfate, but did contain a material amount of aluminum sulfate and but an insignificant proportion of ferric phosphate. It was alleged to be misbranded further in that the therapeutic claims made for it in the booklet entitled "Vitamineral Therapy" and upon the card entitled "Therapy Chart Doctors' Reference Chart," were false and misleading since such statements represented and suggested that the preparation would be beneficial in the treatment, among other things, of endocervicitis, endometritis, vaginitis, polypus, cysts, abnormal tissue, leucorrhea, dysmenorrhea, and amenorrhea, whereas the preparation would not be effective for such conditions.

Examination of a sample of Vitaminerals VM No. 120 showed that the article consisted essentially of aluminum sulfate (approximately 15 percent), iron sulfate (approximately 9 percent), glycerine, and water. The article was alleged to be misbranded in that the statements "containing ferric sulphate" appearing on the carton and bottle labels, and "Vitamineral No. 120 Ferric Sulphate, Ferrous Sulphate and Ferric Phosphate," in the booklet entitled "Vitaminerals Therapy," were false and misleading since the article did not contain any ferric phosphate and since such statements failed to reveal that the article contained a preponderating proportion of the astringent drug, aluminum sulfate. It was alleged to be misbranded further in that the therapeutic claims made for it in the booklet "Vitamineral Therapy" and upon the card "Therapy Chart Doctors' Reference Chart" were false and misleading since the article was not efficacious for these purposes. Some of the representations and suggestions made were that the article would be effective for use in colonic therapy, as a mouth wash, gargle, and swab, for use for trench mouth, and as a nasal douche. It was offered as an eye wash, and for local infections of the ear canal, cuts, sores, hemorrhoids, and gastric ulcers. It was further offered as a primary or secondary supplemental treatment in the following conditions: Acne, acidosis, albuminuria, alcoholic neuritis, ameba, amenorrhea, anemia, angina pectoris, asthenia, asthma, boils, Bright's disease, calculi of the bladder and kidneys, calcium in lenses, catarrh, colitis, colon diseases, corneal ulceration, intestinal and uterine cramps, cystitis, diarrhea, faulty digestion, dysmenorrhea, ear infections, eczema, empyema, endocervicitis, endometritis, enteritis, eye infections, fistula, gall bladder inflammation, gall stone, gastritis, gastro-intestinal disturbances, hay fever, hemeralopia, hemophilia, uterine hemorrhage, hives, impetigo, influenza, intestinal disorders, keratomalacia, kidney disorders, kidney inflammation, laryngitis, leg ulcers, leukorrhea, diseases of the liver, lymph infections, mal petit grand, malaria, malnutrition, excessive, deficient, or painful menstruation, miscarriage, nausea and vomiting of pregnancy, neurasthenia, old age, ophthalmia, orchitis, polypus-vaginal, uterine, and rectal, prostatis, proctitis, psoriasis, pterygium, pyorrhea, lack of resistance, respiratory infections, septicemia, shingles, sinusitis, skin disorder, sty, loose teeth, tetany, tonsilitis, trench mouth, tuberculosis, duodenal, gastric and stomach ulcers, uterine prolapsis, vaginitis, varicose ulcers and veins, tape or helminth worms, and xerophthalmia.

The articles, with exception of VM No. 100, were also alleged to be misbranded under the provisions of the law applicable to foods as reported in food notices of judgment.

On September 21, 1942, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

947. Misbranding of Vitasol The 6–V Health Builder. U. S. v. 107 Jars of "Vitasol The 6–V Health Builder." Default decree of condemnation and destruction. (F. D. C. No. 7484. Sample No. 90189–E.)

On May 11, 1942, the United States attorney for the District of Massachusetts filed a libel against 107 jars of the above-named product at Boston, Mass., alleging that the article had been shipped in interstate commerce on or about April 28, 1942, by the Vitasol Corporation from Brooklyn, N. Y.; and charging that it was misbranded.

The article was labeled in part: "Vitasol * * * Approximate composition of one ounce of Vitasol 1,000 U. S. P. Units Vitamin A, 150 International Units Vitamin B_1, 50 Sherman Bourquin Units Vitamin B_2 (G), 50 International Units Vitamin C, 2,000 U. S. P. Units Vitamin D, added Vitamin E (Wheat Germ) Minerals Grams Per Ounce Calcium—0.160, Iron—0.0067, Phosphorus—0.170 * * * Ingredients Deliciously flavored and skillfully blended with Pure Sugar, Cocoa, Dry Milk Solids, Malted Milk, Barley Malt, Dextrose, Yeast, Soy Bean, Vanillin."

The article was alleged to be misbranded in that the following statements in the labeling: "Vitasol * * * The 6–V Health Builder * * * Dedicated to the Betterment of Health * * * Vitamin A is vital to eyesight. Vitamins B_1, B_2 (G) stimulates the appetite, aids digestion. Vitamin C favors good bone and tooth formation, prevent scurvy. The 'Sunshine Vitamin D' is important to general health, utilizes calcium and phosphorus in building strong teeth and bones. Organic Iron helps increase red corpuscle growth. Yeast as an aid to good blood and body functions. Dextrose for restoring energy. Soy Bean rich in Protein (strength food). * * * Vitasol is a * * * health builder * * * prepared to provide a wide variety of protecting food elements

(not available in the ordinary diet) essential to abundant vitality and health. * * * quick revitalizing food for all active adults. Vitamins Vigor Vitality." were false and misleading since they represented and suggested that the article was capable of building health, was vital to eyesight, would stimulate the appetite, would aid digestion, would insure good bone and tooth formation, would increase the red corpuscle content of the blood, would restore energy, would insure strength and would provide nutritional elements not available in the ordinary diet which are essential to vitality and health, whereas the article would not accomplish the results or fulfill the promises of benefit represented or suggested for it.

The article was also alleged to be misbranded in violation of the provisions of the law applicable to foods, reported in food notices of judgment.

On November 30, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS FOR VETERINARY USE [23]

948. Misbranding of Garmas Powder, Tulas Powder, and Knox-It. U. S. v. Syracuse Pharmacal Co., Inc. Plea of guilty. Fine, $150. (F. D. C. No. 7263. Sample Nos. 74195–E, 74939–E, 74940–E.)

On November 10, 1942, the United States attorney for the Northern District of New York filed an information against the Syracuse Pharmacal Co., Inc., Syracuse, N. Y., alleging shipment on or about July 5 and September 19, 1941, and January 16, 1942, from the State of New York into the States of Pennsylvania and New Jersey of quantities of the above-named drugs which were misbranded. The articles were labeled in part: (Cartons) "Garmas Powder * * * Mastitis Powder * * * Prepared For F. B. Miller & M. F. Miller Veterinarians Montrose, Pa.," "Veterinary Powder * * * Tulas Powder," or "Knox-It * * * Manufactured For Dairy Remedies Company Monroe, Wisconsin Montclair, New Jersey."

Analysis of a sample of the Garmas Powder showed that it consisted essentially of sulfur, methenamine, compounds of calcium, copper, and antimony, plant material, including plant and cereal tissues, starch, and licorice root, iodides, and a trace of iodoform.

The Garmas Powder was alleged to be misbranded in that the statements appearing in its labeling "Mastitis Powder * * * Garmas Powder Treatment for Bloody and Stringy Milk. A well filled tablespoonful of Garmas Powder should be given in each feeding * * * A week or more before calving it is advisable to give once a day to each animal a tablespoonful of Garmas Powder," were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of mastitis in animals, whereas it would not be efficacious for such purposes.

Analysis of a sample of the Tulas Powder showed that it contained 2.98 percent of arsenous acid, salicylic acid, sulfur, and charcoal.

It was alleged to be misbranded in that the statement appearing in its labeling, "An internal treatment for chronic suppurative conditions in animals," was false and misleading since it represented and suggested that the article was efficacious as an internal treatment for chronic suppurative conditions in animals, whereas it was not efficacious as an internal treatment for such conditions.

Analysis of a sample of Knox-It showed that it consisted essentially of plant material, including a cereal, iodoform, methenamine, sulfur, lime, and small proportions of a copper compound, and an iodide.

It was alleged to be misbranded in that the statements appearing in its labeling, "Knox-It For the treatment of common disturbances of the mammary system resulting in thick milk, bloody milk, non-contagious Garget * * * A combination of ingredients which tends to condition milch cows and is favorable in the treatment of disturbances which may result in bloody and stringy milk and non-contagious garget * * * Also tends to build up the resistance of animals against a tendency to simple garget and for this purpose a full tablespoonful may be given daily or oftener, to each animal a week or ten days before calving," were false and misleading since the statements represented and suggested that the article would be efficacious in the cure, mitigation, treatment or prevention of garget or mastitis, whereas it would not be efficacious for such purposes.

[23] See also Nos. 920, 922, 924, for other veterinary remedies.

On May 13, 1943, the defendant having changed its original plea of not guilty to a plea of guilty, the court imposed a fine of $50 on each of the 3 counts, totaling $150.

949. Misbranding of Grange Poke Root and Salt Petre Compound. U. S. v. Dairy Association Co., Inc. Plea of nolo contendere. Fine, $100. (F. D. C. No. 7292. Sample No. 90155–E.)

The labeling of this veterinary preparation contained false and misleading therapeutic claims.

On August 8, 1942, the United States attorney for the District of Vermont filed an information against the Dairy Association Co., Inc., Lyndonville, Vt., alleging shipment on or about August 30, 1941, from the State of Vermont into the State of New Hampshire of a quantity of Grange Poke Root and Salt Petre Compound which was misbranded.

Analysis of the article showed that it consisted essentially of ground root and potassium nitrate.

The article was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of garget, mastitis or fever, were false and misleading since it would not be efficacious for such purposes.

On April 6, 1943, the defendant having entered a plea of nolo contendere, the court imposed a fine of $100.

950. Misbranding of Wasa-Tusa. U. S. v. A. B. Seelye Medical Co. Plea of guilty. Fine, $10 and one-half of the costs. (F. D. C. No. 7747. Sample No. 73654–E.)

On December 12, 1942, the United States attorney for the District of Kansas filed an information against the A. B. Seelye Medical Co., a corporation, Abilene, Kans., alleging shipment on or about January 21, 1942, from the State of Kansas into the State of Missouri of a quantity of the above-named drug which was misbranded.

Analysis showed that the article consisted essentially of small proportions of volatile oils, including camphor, oil of sassafras, and oil of pine, ammonia, capsicum, chloroform and alcohol colored with amaranth.

The article was alleged to be misbranded in that the statements appearing in its labeling, "Swellings, etc., on Animals. For Colic in Horses, Bloating and Diarrhoea in Cattle and Young Calves. Dose 1 teaspoonful to 3 tablespoonfuls in pint of hot water, then repeat in 20 minutes if needed," were false and misleading in that they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of swellings on animals, colic in horses, and bloating and diarrhea in cattle and young calves, whereas it would not be efficacious for such purposes.

On April 12, 1943, the defendant having entered a plea of guilty, the court imposed a fine of $10 and one-half of the costs.

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PRODUCTS

[1] Permanent injunction issued.
[2] Prosecution contested.
[3] Prosecution contested. Contains opinion of the court.
[4] Permanent injunction issued. Contains findings of fact and conclusions of law.

SHIPPERS AND MANUFACTURERS

[1] Permanent injunction issued.
[2] Prosecution contested.
[3] Prosecution contested. Contains opinion of the court.
[4] Permanent injunction issued. Contains findings of fact and conclusions of law.
[5] Contains opinion of the court.

[1] Permanent injunction issued.

[5] Contains opinion of the court.

U. S. GOVERNMENT PRINTING OFFICE: 1944

D. D. N. J., F. D. C. 951–1000 Issued November 1944

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

951–1000

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *August 21, 1944.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

951. Misbranding of Improved Cold Tablets. U. S. v. 126 Packages of Improved Cold Tablets. Default decree of condemnation and destruction. (F. D. C. No. 8936. Sample No. 26201–F.)

On December 2, 1942, the United States attorney for the Northern District of Indiana filed a libel against 126 packages of Improved Cold Tablets at Fort Wayne, Ind., alleging that the article had been shipped in interstate commerce on or about September 14, 1942, by the Hygenol Co. from Minneapolis, Minn.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of acetanilid 1½ grains per tablet, camphor monobromated, cinchonidine sulfate, capsicum, caffeine, and extracts of plant drugs, including a laxative drug.

The article was alleged to be misbranded (1) in that the statements appearing upon its label, "Cold Tablets * * * For the Relief from Common Head Colds, * * * For the relief of distress and discomfort due to Common Head Colds, etc.," were false and misleading since such statements represented and suggested that the article was effective in the treatment of head colds, whereas it was not so effective; (2) in that its labeling failed to bear ade-

*For omission of, or unsatisfactory, ingredients statements, see Nos. 954, 956, 961, 991, 994; inconspicuousness of required label information, No. 958; cosmetic, subject to the drug provisions of the Act, No. 992.

quate directions for use since the directions appearing on the label provided for an excessive amount of acetanilid and were therefore not adequate for an article of such composition; (3) in that its labeling failed to bear such adequate warnings against use by children, and in those pathological conditions wherein its use might be dangerous to health, in such manner and form as are necessary for the protection of users, since the article was a laxative and its labeling failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and since the article contained acetanilid and its labeling failed to warn against use by children; (4) in that its labeling failed to bear such adequate warnings against unsafe dosage and methods and duration of administration in such manner and form as are necessary for the protection of users, since its labeling failed to warn that frequent or continued use of a preparation containing acetanilid might cause serious blood disturbances, anemia, collapse, or a dependence on the drug, and since its labeling also failed to warn that frequent or continued use of a laxative might result in dependence upon laxatives; and (5) in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling thereof, since the article, when taken in accordance with the directions appearing on the labeling, "Directions Adults: Take 2 tablets every 2 or 3 hours until bowels move freely, then take 1 or 2 tablets 3 or 4 times a day until relieved. Warning! Do Not Take More Than Six Tablets In Any Twenty-Four Hour Period," would provide, even with the limitation of 6 tablets a day, a maximum of 9 grains of acetanilid a day for an indefinite period of time, and was dangerous to health.

On April 5, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

952. Misbranding of triple bromide tablets. U. S. v. 11⅔ Dozen Packages of Triple Bromide Tablets. Decree of condemnation and destruction. (F. D. C. No. 8967. Sample No. 17109-F.)

On December 5, 1942, the United States attorney for the Northern District of New York filed a libel against 11⅔ dozen packages of triple bromide tablets at Albany, N. Y., alleging that the article had been shipped in interstate commerce on or about September 21, 1942, from Chicago, Ill., by the Savoy Drug & Chemical Co.; and charging that it was misbranded. The article was labeled in part: "Wards 50 Triple Bromide Tablets * * * Distributed by Montgomery Ward & Co."

Examination showed that the article contained a total of 15 grains per tablet of the combined sodium, potassium, and ammonium bromides.

It was alleged to be misbranded in that it was dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling thereof, "Adult Dose: One tablet three times daily."

On January 23, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

953. Adulteration and misbranding of solution of magnesium citrate. U. S. v. 222 Bottles of Effervescing Solution Citrated Magnesia. Default decree of condemnation and destruction. (F. D. C. No. 8388. Sample No. 19441-F.)

This product was sold under a name recognized in the United States Pharmacopoeia and its strength, quality, and purity differed from the standard prescribed in such authority. It was a laxative and its labeling failed to warn that it should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, or that frequent or continued use might result in dependence upon a laxative to move the bowels.

On September 22, 1942, the United States attorney for the District of Rhode Island filed a libel against 222 bottles of the above-named product at Providence, R. I., alleging that the article had been shipped on or about August 5, 1942, by the White-Stone Laboratories from Boston, Mass.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from and its

*See also No. 951.

quality and purity fell below the standard set forth therein since it did not contain, in each 100 cc., magnesium citrate corresponding to not less than 1.6 grams of magnesium oxide, as provided in the Pharmacopoeia, but contained Epsom salt (magnesium sulfate) corresponding to 1.14 grams of magnesium oxide per 100 cc.; and it possessed 1/16 of the quantity of citric acid and approximately ½ of the quantity of sucrose required in the Pharmacopoeia for solution of magnesium citrate.

It was alleged to be misbranded in that is labeling failed to bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users.

On October 19, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

954. Adulteration and misbranding of miscellaneous drugs. U. S. v. 223 Cases of Miscellaneous Foods, Drugs, and Cosmetics. Decree of condemnation. Products ordered released under bond for reprocessing and relabeling good portion. (F. D. C. No. 8509. Sample No. 28246–F.)

Some of these products had been water-damaged and others were very old and deteriorated. They included, among other items, proprietary medicines and surgical dressings.

On October 5, 1942, the United States attorney for the Northern District of Georgia filed a libel against 223 cases of miscellaneous foods, drugs, and cosmetics at Atlanta, Ga., alleging that the articles had been shipped on or about September 16, 1942, by Wells and Harris from Norfolk, Va.; and charging that the drug items were adulterated and misbranded.

The drug items were alleged to be adulterated in that water had been mixed therewith so as to reduce their quality.

They were alleged to be misbranded (1) in that the labeling of some of the items contained false and misleading statements regarding the curative or therapeutic effects of the articles; (2) in that some of the items failed to bear labels containing an accurate statement of the quantity of contents of the packages; (3) in that the labels of some of the items did not bear the common or usual name of the active ingredients of the articles; and (4) in that the labeling of some of the items did not bear adequate warnings against use in those pathological conditions wherein their use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users.

The food and cosmetic items were alleged to be adulterated under the provisions of the law applicable to foods and cosmetics as reported in the notices of judgment on foods and on cosmetics.

On October 12, 1942, John W. Harris, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the products were ordered released under bond for segregation and destruction of the unfit portion, and for reprocessing and relabeling of the good portion under the supervision of the Food and Drug Administration.

955. Misbranding of Bi-Sal Tablets. U. S. v. 237 Bottles of Bi-Sal Tablets. Default decree of condemnation and destruction. (F. D. C. No. 9051. Sample No. 37708–F.)

On December 24, 1942, the United States attorney for the Northern District of Illinois filed a libel against 237 bottles of Bi-Sal Tablets at Chicago, Ill., alleging that the article had been shipped on December 3, 1942, in interstate commerce from Cleveland, Ohio, by Oxford Products, Inc.; and charging that it was misbranded.

Analysis showed that the article contained phenolphthalein, extracts of plant drugs, including capsicum (cayenne pepper), bile extract, and an alkaloid-bearing drug, such as nux vomica.

The article was alleged to be misbranded in that the name "Panogestic Enzymes with Bile Salts Compound" was misleading since the article was essentially a laxative and its physiologic effect was due principally to phenolphthalein, which is neither an enzyme nor a bile constituent, but is a coal tar derivative. The article was alleged to be misbranded further (1) in that the statement appearing in its labeling, "This combination is used * * * in certain forms of Gall Bladder and Bile Duct Infections," was false and misleading since the statement represented and suggested that the article was effective in the treatment of certain forms of gall bladder and bile duct infections, whereas it was not an effective

treatment for any form of such infections, but was essentially a laxative; and (2) in that its labeling failed to bear adequate directions for use since the directions appearing in the labeling "2 tablets about 2 hours after Breakfast and 2 tablets at Bedtime" represented and suggested that the article be taken repeatedly, whereas a laxative should not be directed to be taken repeatedly and such representation and suggestion was not corrected by the label statement "To avoid the 'laxative habit' do not take continuously."

On March 29, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

956. Misbranding of My Prescription, and Pink-etts. U. S. v. 23 Packages of My Prescription. Default decree of condemnation and destruction. (F. D. C. No. 8863. Sample No. 19021–F.)

On November 16, 1942, the United States attorney for the District of New Jersey filed a libel against 23 packages, each package containing a bottle of liquid labeled in part "My Prescription" and an envelope containing 3 pills labeled in part "Pink-etts," at Newark, N. J., alleging that the articles had been shipped in interstate commerce on or about October 27, 1942, from Honesdale, Pa., by F. X. Crockenberg; and charging that they were misbranded.

Examination of samples of the articles showed that the "My Prescription" consisted essentially of bismuth and ammonium compounds, including citrates, sugar, gum, ginger, and water, and that the "Pink-etts" contained a laxative plant drug.

The articles were alleged to be misbranded in that the statements appearing in their labeling, (carton and bottle label) "For Your Stomach A Remedy For Stomach Ills * * * Corrective and Digestant, used in the treatment of Gastric and Duodenal Ulcers," (labels for Pink-etts) "For * * * Liver Trouble, Etc.," (circular) "Stomach Disorders and Their Causes Gastric and Duodenal Ulcers Gastritis Indigestion Gas Pains and all Stomach Disorders 'My Prescription' has been successfully used by hundreds of users. * * * We recommend the use of at least three bottles for permanent relief. * * * The story on the following pages gives you some idea as to the symptoms of stomach disorders and how they are treated. In taking 'My Prescription' all that is necessary is to avoid the things that you know are harmful, in order to give the medicine a quicker and better action," and other circular statements discussing stomach ulcer, were false and misleading since such statements represented and suggested that "My Prescription" was effective in the treatment of diseases of the stomach, and that the "Pink-etts Pills" were effective in the treatment of liver trouble and various conditions included in the designation "etc", whereas the articles were not effective for such purposes.

Further misbranding was alleged in that both products were drugs in package form and their labels failed to bear accurate statements of the quantity of the contents contained therein; and in that the "Pink-etts" were fabricated from two or more ingredients and the label failed to bear the common or usual name of each active ingredient, and in that the labeling failed to bear such adequate warnings against use of the article in those pathological conditions wherein its use might be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form as are necessary for the protection of users, since the article was a laxative and its labeling failed to warn that a laxative should not be taken in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and that frequent or continued use might result in dependence upon laxatives to move the bowels.

On January 4, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

957. Misbranding of Natur-Pep. U. S. v. 80 Bottles of Natur-Pep. Decree of destruction. (F. D. C. No. 8688. Sample No. 2642–F.)

Examination showed that the article consisted essentially of Epsom salt (30.9 percent), water, small amounts of iron phosphate, sodium and potassium compounds, methenamine, a salicylate, and extracts of plant drugs including a laxative plant drug.

On or about November 9, 1942, the United States attorney for the Western District of Missouri filed a libel against 80 bottles of Natur-Pep at Kansas City, Mo., alleging that the article had been shipped in interstate commerce from Kansas City, Kans., by the Curts-Folse Laboratories; and charging that it was misbranded.

The article was alleged to be misbranded in that certain statements appearing in its labeling which represented and suggested that the article was not habit-forming, gave "pep," was effective in the treatment of stomach, liver, kidney, blood, nerve, and intestinal disorders, and was effective in the treatment of constipation, swollen limbs, and indigestion, were false and misleading since the article was capable of causing laxative-habit formation, did not give "pep," and was not effective in the treatment of the disorders and conditions above-described; and in that the statement appearing in its labeling, "Natur-Pep Tonic Is Prepared From Ingredients of Recognized Medicinal Value: Extract Cascara Sagrada, Iron Pyrophosphate, Strontium Salicylate, Oleum Coriander, Methyl Salicylate, Extract Gentian, Alcohol ½%, Hexamethylenamine, Extract Glycyrrhiza, Magnesium Sulphate, Potassium Acetate, Sodium Salicylate, Oleum Anise, Glycerine," was misleading since such statement created the impression that the article provided significant quantities of all the ingredients named, whereas it did not provide significant quantities of such ingredients, but was essentially an Epsom salt laxative. It was alleged to be misbranded further in that its labeling failed to bear adequate directions for use since the article was a laxative and the directions which appeared in the labeling provided for continuous administration, whereas a laxative should not be used continuously; and in that the labeling failed to bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or adequate warnings against unsafe methods and duration of administration, in such manner and form as are necessary for the protection of users, since the labeling failed to bear a warning that a laxative should not be taken in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and that frequent or continued use might result in dependence upon a laxative to move the bowels.

On December 16, 1942, no claimant having appeared, judgment was entered ordering that the product be destroyed.

958. Misbranding of Ramazzotti. U. S. v. 3 Cases of Ramazzotti. Consent decree of condemnation. Product ordered released under bond for relabeling. (F. D. C. No. 8615. Sample Nos. 17361–F, 18845–F.)

On or about October 22, 1942, the United States attorney for the District of Connecticut filed a libel against 3 cases, each containing 24 bottles, of Ramazzotti at Stamford, Conn., alleging that the article had been shipped in interstate commerce on or about July 24, 1942, by the Banfi Products Corporation from New York, N. Y.; and charging that it was misbranded.

Examination showed that the article contained extracts of plant drugs, including a laxative drug such as rhubarb, and 38.2 percent of alcohol.

The article was alleged to be misbranded in that the statement "originated by FLLI. RAMAZZOTTI, MILANO, ITALY" and various other statements in the Italian language, together with designs including the Papal seal and the State seal of Italy, appearing in the labeling, were false and misleading since they created the impression that the article was prepared in Milan, Italy, whereas it was manufactured in New York, N. Y.

The article was alleged to be misbranded further (1) in that the statements on the bottle label, "FAMOUS SINCE 1815," and on the bottle wrapper, "Used throughout the World since 1815," were false and misleading since the article had not been produced and marketed over the period since 1815; (2) in that the name of each active ingredient, including the name and quantity or proportion of alcohol contained in the article, required by law to be declared on the label, was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, and devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the names of the active ingredients and the quantity or proportion of alcohol did not appear on the bottle wrapper and did not appear in the Italian language in any of the labeling; and (3) in that its labeling failed to bear adequate directions for use since the directions in English, "Dose: ½ to 1 oz. taken straight, in black coffee, or hot lemonade before or after meals, upon retiring or any time during the day," and the directions in Italian "puro e misto all'acqua, al seltz, alle acque minerali, al Vermouth e col caffe" (translation: "pure and mixed with water, seltzer, with mineral waters, with Vermouth and with coffee"), did not provide for a definite amount of frequency or duration of administration, but were indefinite and therefore not adequate.

It was alleged to be misbranded further in that its labeling failed to bear adequate warnings against use in those pathological conditions, or by children, wherein its use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of the user, since its labeling bore no warning against use by children for whom, by reason of its large proportion of alcohol, it would be especially unsuitable; its labeling bore no warning against use in case of abdominal pain, nausea, vomiting, or other symptoms of appendicitis, whereas, by reason of its content of a laxative drug such as rhubarb it would be dangerous when used in such circumstances; and it bore no warning against frequent or continued use which might result in the establishment of dependence upon laxatives to move the bowels.

On January 7, 1943, Banfi Products Corporation, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of and in form satisfactory to the Food and Drug Administration.

959. Misbranding of Special SC Pink Tablets. U. S. v. 3 Drums of Special SC Pink Tablets. Product relabeled and ordered released to claimant. (F. D. C. No. 8428. Sample Nos. 4628–F to 4630–F, incl.)

On September 29, 1942, the United States attorney for the Middle District of Tennessee filed a libel against 3 drums containing a total of approximately 140,000 Special SC Pink Tablets at Nashville, Tenn., alleging that the article had been shipped in interstate commerce on or about February 19, April 25, and June 23, 1942, by Charles H. Dietz, Inc., from St. Louis, Mo.; and charging that it was misbranded.

Analyses of samples showed that the article consisted essentially of acetanilid, potassium bromide, laxative plant drugs, and cinchonidine sulfate.

The article was alleged to be misbranded in that its labeling failed to bear adequate directions for use, since there were no directions. It was alleged to be misbranded further in that its labeling failed to bear adequate warnings against use in those pathological conditions, or by children, wherein its use might be dangerous to health, in such manner and form as are necessary for the protection of users, since the article was a laxative and its labeling failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis; that frequent or continued use of the article might result in dependence on a laxative; and that the article was not to be given to children. It was alleged to be misbranded further in that its labeling failed to bear adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users, since the labeling failed to warn that frequent or continued use of acetanilid might be dangerous, causing serious blood disturbances, anemia, collapse, or a dependence on the drug, and that not more than the recommended dosage was to be taken.

On October 9, 1942, the product having been relabeled and the claimant, the Gattis Chemical Co., Nashville, Tenn., having paid costs of the proceedings, the product was ordered delivered to the claimant.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH*

960. Adulteration of sulfanilamide tablets. U. S. v. 3,000 Bottles of Sulfanilamide Tablets. Consent decree of condemnation. Product ordered released under bond for segregation and destruction or reprocessing of the contaminated portion. (F. D. C. No. 8962. Sample No. 18441–F.)

Examination of a sample of this product showed that most of the tablets were covered with live mold, a species of Aspergillus.

On December 9, 1942, the United States attorney for the Eastern District of New York filed a libel against 3,000 bottles, each containing 1,000 tablets, of sulfanilamide at Brooklyn, N. Y., alleging that the article had been shipped in interstate commerce on or about November 18, 1942, by the Maltbie Chemical Co., Newark, N. J.; and charging that it was adulterated in that it consisted in whole or in part of a filthy substance.

On December 26, 1942, the Maltbie Chemical Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be sorted according to codes and the portion

*For bacterial contamination see Nos. 970–977, 985, 986.

found contaminated either destroyed or reprocessed. Any of the product so reprocessed was to be further examined and, if not fit for human or medical use, to be destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

961. Adulteration of Dr. Fenton's Necrocide Special Prescription No. 2 and misbranding of Dr. Fenton's Neumoade Special Prescription No. 1, Special Prescription No. 4, Diarrhostringent Special Prescription No. 8, Special Prescription No. 11, and Ovotone. U. S. v. Lois Swarzentruber and Venita Smith (Dr. Fenton's Vigortone Co.). Pleas of guilty. Fines, $100 and costs. (F. D. C. No. 6473. Sample Nos. 38909–E, 38910–E, 38919–E, 58422–E, 58423–E, 58425–E.)

Dr. Fenton's Necrocide Special Prescription No. 2 exceeded its own declared standard of strength. The labeling of the other veterinary products here involved bore false and misleading therapeutic claims and, with the exception of Dr. Fenton's Neumoade Special Prescription No. 1, failed to give the common or usual names of the active ingredients. Dr. Fenton's Neumoade Special Prescription No. 1 and Diarrhostringent Special Prescription No. 8 did not bear proper statements on their labels in regard to the quantity of contents.

On April 12, 1943, the United States attorney for the Northern District of Iowa filed an information against Lois Swarzentruber and Venita Smith, trading as Dr. Fenton's Vigortone Co., Cedar Rapids, Iowa, alleging shipments on or about January 7 and 20, and February 18, 1941, from the State of Iowa into the State of Minnesota of various quantities of the above-named drugs, one of which, the "Dr. Fenton's Necrocide Special Prescription No. 2," was adulterated and the remainder of which were misbranded.

Analysis of the Neumoade Special Prescription No. 1 showed that it consisted essentially of copper sulfate, Epsom salt, naphthalene, small proportions of iodide, chromate, silica compounds and plant material including capsicum and anise.

It was alleged to be misbranded in that certain statements appearing in its labeling which represented and suggested that, when used as directed, it was an antiseptic, antiferment, expectorant, resolvent, antipyretic, alterative, and sedative, were false and misleading since, when used as directed, it was not an antiseptic, antiferment, expectorant, resolvent, antipyretic, alterative, or sedative. It was alleged to be misbranded further in that the label affixed to its container failed to bear a statement of the quantity of the contents of the container in terms of weight, measure, or numerical count.

Analysis of the Necrocide Special Prescription No. 2 showed that it contained not less than 50.6 percent of copper sulfate in addition to Epsom salt, small proportions of methylene blue, plant material including capsicum, an iodide, and a dichromate compound.

It was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess since it was represented to contain not more than 25 percent of copper sulfate, whereas it contained not less than 50.6 percent of copper sulfate.

Analysis of the Special Prescription No. 4 showed that it consisted essentially of Epsom salt, copper sulfate (5.36 percent, sodium chromate, charcoal, and plant material including capsicum and anise.

It was alleged to be misbranded in that certain statements appearing in its labeling which represented and suggested that, when used as directed, it was a heart stimulant, a stomachic, an alterative, a resolvent, a deobstruent, and a diuretic; that another drug, "Dr. Fenton's Santonin Powder No. 7," would be efficacious in the removal of large and small roundworms infesting the stomach and small intestines of hogs and pigs; and that another drug, "Vigortone," would increase the vigor and tone of the system, were false and misleading since the drug, when used as directed, was not a heart stimulant or a stomachic, alterative, resolvent, deobstruent, or diuretic, and the other drugs named would not be efficacious for the purposes claimed.

Analysis of the Diarrhostringent Special Prescription No. 8 showed that it consisted essentially of charcoal, carbonate salt, brownish water–soluble organic material, copper sulfate 0.93 percent, and a small proportion of Epsom salt.

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*See also Nos. 953, 954.

It was alleged to be misbranded in that certain statements in its labeling which represented and suggested that, when mixed with feed as directed and when administered together with another drug, "Dr. Fenton's Health Pep," it would act as a tonic and would tone up the system of poultry and would act as a diarrhostringent, that is, an astringent in diarrhea of poultry, were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further in that it was in package form and its label failed to bear an accurate statement of the quantity of the contents.

Analysis of Special Prescription No. 11 showed that it was in the form of tablets which contained copper sulfate and mercuric chloride, approximately 2½ grains of each ingredient per tablet.

It was alleged to be misbranded in that certain statements in its labeling which represented and suggested that, when used as directed, it would be efficacious in the cure, mitigation, treatment, or prevention of some bowel affections in poultry; that it would act as an intestinal antiseptic, a stimulant, a vermifuge, an hepatic stimulant, and as an alterative, and that another drug, "Vigortone," would increase the vigor and tone of the system, were false and misleading since it and the other drug named would not be efficacious for the purposes claimed.

Analysis of the Ovotone showed that it consisted essentially of sodium sulfate, salt, sulfur, calcium carbonate, copper sulfate, small proportions of iron oxide, Epsom salt, and plant material, including tobacco and anise.

It was alleged to be misbranded in that certain statements in its labeling which represented and suggested that it was efficacious in the prevention or removal of stomach worms in sheep and of large, small, and roundworms in sheep, and that another drug, "Vigortone," would increase the vigor and tone of the system, were false and misleading since it and the other drug named would not be efficacious for the purposes claimed.

The Special Prescription No. 4, Diarrhostringent Special Prescription No. 8, Special Prescription No. 11, and Ovotone, were alleged to be misbranded further in that they were not designated solely by names recognized in an official compendium and were fabricated from two or more ingredients and their labels failed to bear statements of the common or usual name of each active ingredient thereof.

On April 12, 1943, the defendants having entered pleas of guilty, the court imposed a fine of $50 and costs upon each of the 2 defendants.

962. Adulteration and misbranding of Elixir Quinux. U. S. v. S. F. Durst & Co., Inc., and Richard L. Durst. Pleas of nolo contendere. Fines, $205. (F. D. C. No. 8735. Sample No. 54944–E.)

On December 30, 1942, the United States attorney for the Eastern District of Pennsylvania filed an information against S. F. Durst & Co., Inc., Philadelphia, Pa., and Richard L. Durst, alleging shipment on or about March 20, 1942, from the State of Pennsylvania into the State of New Jersey of a quantity of Elixir Quinux which was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, since it purported and was represented to contain 2 grains of quinine sulfate per fluid ounce, whereas it contained not more than 0.42 grain of quinine sulfate per fluid ounce.

It was alleged to be misbranded in that the statement borne on its label "Each fluid ounce represents: * * * Quinine Sulphate 2 grs." was false and misleading.

On January 13, 1943, the defendants having entered pleas of nolo contendere, the court found them guilty and imposed a fine of $200 against the corporation and a fine of $5 against the individual defendant.

963. Adulteration and misbranding of iron glycerophosphate compound. U. S. v. Associated Laboratories, Inc. Plea of nolo contendere. Defendant found guilty. Fine, $100. (F. D. C. No. 8736. Sample No. 77054–E.)

On December 30, 1942, the United States attorney for the Eastern District of Pennsylvania filed an information against the Associated Laboratories, Inc., Philadelphia, Pa., alleging shipment on or about May 14, 1942, from the State of Pennsylvania into the State of New Jersey of a quantity of iron glycerophosphate compound which was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it purported and was represented to contain, in each cubic centi-

meter, ⅓ grain of iron cacodylate, whereas it contained in each cubic centimeter not more than a trace of iron cacodylate.

It was alleged to be misbranded in that the statement in its labeling "1 cc. Represents: * * * Iron Cacodylate * * * ⅓ gr.," was false and misleading.

On January 13, 1943, the defendant having entered a plea of nolo contendere, the court found the defendant guilty and imposed a fine of $100.

964. Adulteration and misbranding of wheat germ. U. S. v. The Battle Creek Food Co. Plea of guilty. Total fine, $600. (F. D. C. No. 8800. Sample Nos. 91743–E, 16873–F, 16874–F.)

On March 23, 1943, the United States attorney for the Eastern District of Michigan filed an information against the Battle Creek Food Co., Battle Creek, Mich., alleging shipment on or about June 1 and 15 and August 28, 1942, from the State of Michigan into the States of New York and Illinois of quantities of wheat germ that was adulterated and misbranded.

Examination of samples of the article showed that it contained not more than 250 U. S. P. units of vitamin B_1 per ounce, which is approximately ¾ the minimum daily requirement for an adult.

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess, 500 U. S. P. units of vitamin B_1 per ounce.

It was alleged to be misbranded in that the statement in its labeling "One ounce (approx. ⅓ cup) of Battle Creek Wheat Germ supplies 500 U. S. P. units of vitamin B_1 (Thiamin), (1½ times the minimum daily requirement for an adult)," was false and misleading since the article did not contain 500 U. S. P. units of vitamin B_1 per ounce, and 1 ounce of the article would not furnish 1½ times the minimum daily requirement of vitamin B_1 for an adult, but would furnish only half that amount.

The article was alleged to be misbranded further in that the statement, "Wheat Germ fills a much needed place in the modern diet which is apt to be deficient in Thiamin (vitamin B_1) and Riboflavin (vitamin G) * * * Battle Creek Wheat Germ presents * * * economical source of these important vitamins," borne on its label, was misleading since the statement created in the mind of the reader the impression that all modern diets were apt to be deficient in thiamin and riboflavin, and that all modern diets should be supplemented by wheat germ or substances containing thiamin and riboflavin, and that wheat germ is an economical and satisfactory source of riboflavin, whereas thiamin and riboflavin are present in a wide variety of ordinary foods and are present in many ordinary diets in adequate amounts, and all diets do not ordinarily require wheat germ to supplement the need for such vitamins and, in those instances where the dietary intake of riboflavin is inadequate, wheat germ does not provide an economical or satisfactory source of riboflavin.

It was alleged to be misbranded further in that the statement, "Vitamin B_1 tends to make steady nerves, improves appetite, aids digestion and combats constipation. Vitamin G promotes good nutrition; both vitamins help to build vital resistance," borne on its label, was misleading since the statement suggested and created in the mind of the reader the impression and belief that unsteady nerves, poor appetite, poor digestion, constipation, poor nutrition, and low vital resistance are frequently caused by lack of thiamin and riboflavin, and that the reader might reasonably expect that the article would be efficacious to steady the nerves, improve the appetite, aid digestion, combat constipation, promote good nutrition, and build vital resistance, whereas such conditions usually result from causes other than lack of thiamin and riboflavin and the reader might not reasonably expect that the article would be efficacious to correct them since it would rarely be efficacious for such purposes.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods as reported in the notices of judgment on foods.

On April 7, 1943, the defendant entered a plea of guilty and the court imposed a fine of $100 on each of the 6 counts, a total of $600.

965. Adulteration and misbranding of amino acids parenteral. U. S. v. 113 Dozen of Amino Acids Parenteral Stearns. Decree of destruction. (F. D. C. No. 8643. Sample No. 2734–F.)

This product was represented in its labeling as a 15-percent solution of amino acids derived from the acid hydrolysis of casein fortified with tryptophan, and the

tryptophan content of the product was represented as 1 percent of the total amino acids. Examination showed that the product contained approximately one-third of the amount of tryptophan declared.

On or about October 28, 1942, the United States attorney for the Western District of Missouri filed a libel against 11¾ dozen of the above-named product at Kansas City, Mo., alleging that the article had been shipped in interstate commerce on or about September 23, 1942, from Detroit, Mich., by Frederick Stearns and Co.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess on its label, "Amino Acids, 15 percent solution, Tryptophane 1% of Amino Acids."

It was alleged to be misbranded in that the statements appearing in its labeling, (carton) "Amino Acids * * * 15 percent solution * * * Tryptophane 1.0% of Amino Acids," (circular inside carton) "Each batch of Amino Acid Stearns is standardized according to the following average analysis Tryptophane added (1% total Amino Acids) 1%," were false and misleading since the article did not contain the amount of tryphtophan stated.

On January 26, 1943, no claimant having appeared, judgment was entered ordering that the product be destroyed.

966. Adulteration and misbranding of collodion. U. S. v. 10 cartons and 1,500 Bottles of Collodion. Decrees of condemnation and destruction. (F. D. C. No. 8247, 8858. Sample No. 77–F, 25102–F, 25119–F.)

On August 27 and November 12, 1942, the United States attorneys for the Northern District of Illinois and the Eastern District of Virginia filed libels against 1,500 bottles of collodion at Chicago, Ill., and 10 cartons, each containing 250 1-ounce bottles, of collodion at Richmond, Va., alleging that the article had been shipped within the period from on or about June 11 to September 5, 1942, from New York, N. Y., by the Conray Products Co.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that a mixture containing the ester, amyl acetate, had been substituted for collodion U. S. P.

It was alleged to be misbranded in that the statement on its label "Collodion U. S. P." was false and misleading since the article did not have the composition specified by the United States Pharmacopoeia for collodion.

On December 5, 1942, and January 6, 1943, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

967. Adulteration and misbranding of iron compound and yeast tablets. U. S. v. 4 Drums of Iron Compound and Yeast Tablets. Default decree of condemnation and destruction. (F. D. C. No. 8307. Sample No. 4811–F.)

On September 2, 1942, the United States attorney for the Northern District of Ohio filed a libel against 4 drums, each containing approximately 47,300 of the above-named tablets at Cleveland, Ohio, alleging that the article had been shipped in interstate commerce on or about February 14, 1942, by the Keith Victor Pharmacal Co., St. Louis, Mo.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess.

It was alleged to be misbranded in that the following statements on its label, "Each tablet contains B_1 (Thiamin Chloride) 50 International Units B_2 (Riboflavin) 25 Gamma," were false as applied to an article that contained not more than 25 International Units of vitamin B_1 per tablet, and not more than 15 gamma of riboflavin.

The article was also alleged to be adulterated and misbranded under the provisions of law applicable to foods as reported in notices of judgment on foods.

On October 16, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

968. Adulteration and misbranding of DPS Formula 50. U. S. v. 120 Bottles of DPS Formula 50. Default decree of condemnation and destruction. (F. D. C. No. 8407. Sample No. 13007–F.)

Examination showed that this product contained 230 micrograms (gammas) of riboflavin per tablet.

On September 26, 1942, the United States attorney for the District of Oregon filed a libel against 120 bottles, each containing 90 tablets, of DPS Formula 50 at

Portland, Oreg., alleging that the article had been shipped on or about June 19 and July 9, 1942, from Los Angeles, Calif., by the Dartell Laboratories; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, namely, vitamin B_2 (riboflavin) 348 gammas (micrograms).

It was alleged to be misbranded in that the statement appearing on its label, "Each Tablet Contains Not Less Than: * * * Vitamin B_2 348 Gammas," was false and misleading.

The article was also alleged to be adulterated and misbranded under the provisions of law applicable to foods as reported in the notices of judgment on foods.

On November 4, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

969. Adulteration and misbranding of pituitary solution posterior lobe. U. S. v. 332 Boxes of Pituitary Solution Posterior Lobe. Decree of condemnation and destruction. (F. D. C. No. 8885. Sample No. 29212-F.)

Examination of this product showed that 1 cubic centimeter produced an activity upon the isolated uterus of the virgin guinea pig corresponding to 160 percent of that produced by 0.005 gram of standard powdered posterior pituitary, whereas the eleventh revision of the United States Pharmacopoeia, which was official at the time the goods described were shipped, provided that "One cubic centimeter of Solution of Posterior Pituitary produces an activity upon the isolated uterus of the virgin guinea pig, corresponding to * * * not more than 120 percent of that produced by 0.005 Gm. of the Standard Powdered Posterior Pituitary."

On November 18, 1942, the United States attorney for the Northern District of Georgia filed a libel against 332 boxes, each containing 6 ampuls, of pituitary solution posterior lobe at Atlanta, Ga., alleging that the article had been shipped or about September 23, 1942, from Detroit, Mich., by Parke, Davis and Co.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which was recognized in an official compendium, the United States Pharmacopoeia, Eleventh Revision, but its strength differed from the standard set forth in such compendium since it produced an activity in excess of the maximum permitted by the standard set forth therein.

It was alleged to be misbranded in that the statement appearing in its labeling "Pituitary Solution, Posterior Lobe, U. S. P." was false and misleading as applied to the article since its potency was greater than the maximum permitted by the United States Pharmacopoeia, Eleventh Revision.

On April 12, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

970. Adulteration and misbranding of absorbent cotton. U. S. v. 14⅝ Gross Packages of Absorbent Cotton. Decree of condemnation. Product ordered delivered to a local hospital. (F. D. C. No. 8932. Sample No. 22963-F.)

On November 27, 1942, the United States attorney for the Eastern District of Pennsylvania filed a libel against 14⅝ gross packages of absorbent cotton at Philadelphia, Pa., alleging that the article had been shipped on or about October 16, 1942, from Columbia, S. C., by New Aseptic Laboratories, Inc.; and charging that it was adulterated and misbranded. The article was labeled in part: "Superb Absorbent Cotton Sterlized After Packing."

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, but its quality and purity fell below the standard set forth therein since it did not conform to the requirements of the test for sterility of solids, as provided by the Pharmacopoeia, but was contaminated with viable gram-positive bacilli.

It was alleged to be misbranded in that the statement "Sterilized After Packing," appearing on its label, was false and misleading since the article was contaminated as indicated above.

On January 2, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a local hospital. The word "Sterilized" was removed from the label and the product was dispensed as unsterile cotton.

971. Adulteration and misbranding of absorbent cotton. U. S. v. 8 11/12 Gross Packages of Absorbent Cotton. Decree of condemnation and destruction. (F. D. C. No. 8880. Sample No. 5757–F.)

On November 13, 1942, the United States attorney for the Eastern District of Missouri filed a libel against 8 11/12 gross packages of absorbent cotton at St. Louis, Mo., alleging that the article had been shipped in interstate commerce on or about September 25, 1942, by the Hampton Manufacturing Co. from Carlstadt, N. J.; and charging that it was adulterated and misbranded. The article was labeled in part: "Blue Cross * * * Sterilized Absorbent Cotton U. S. P."

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in an official compendium, the United States Pharmacopoeia, but its quality and purity fell below the standard set forth therein since it did not conform to the requirements of the test for sterility of solids as provided in such compendium, but was contaminated with viable aerobic and anaerobic or facultative anaerobic micro-organisms.

It was alleged to be misbranded in that the statements appearing in its labeling "Sterilized Absorbent Cotton U. S. P. Sterilized After Packaging the Cotton in This Package Has Been Prepared Under Strict Sanitary Supervision, Carefully Packed and Sterilized, Making It Safe for Surgical or Household Use" were false and misleading as applied to an article that was not sterilized.

On December 15, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

972. Adulteration and misbranding of bandage gauze compresses. U. S. v. 8,499 Packages of Bandage Gauze Compresses. Decree of condemnation. Product ordered released under bond for resterilization and repackaging. (F. D. C. No. 9005. Sample No. 31618–F.)

On December 14, 1942, the United States attorney for the Southern District of Ohio filed a libel against 8,499 packages of bandage gauze compresses at Columbus, Ohio, alleging that the article had been shipped in interstate commerce on or about October 24, 1942, from Boston, Mass., by A. E. Halperin Co., Inc.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its purity or quality fell below that which it purported or was represented to possess, namely, "sterilized."

It was alleged to be misbranded in that the statement "sterilized," appearing in its labeling, was false and misleading since such statement represented and suggested that the article was sterile, whereas, it was not sterile but was contaminated with viable bacilli and cocci.

On April 16, 1943, A. E. Halperin Co., Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be resterilized and repackaged under the supervision of the Food and Drug Administration.

973. Adulteration and misbranding of sutures. U. S. v. 2,880, 2,880, and 1,980 Tubes of Sutures. Consent decree of condemnation. Product ordered released under bond to be resterilized. (F. D. C. No. 8499. Sample No. 32801–F.)

On October 6, 1942, the United States attorney for the Northern District of New York filed a libel against 7,740 tubes of sutures at Binghamton, N. Y., alleging that the article had been shipped in interstate commerce on or about August 25, 1942, from Boston, Mass., by Flanders-Day Co.; and charging that it was adulterated and misbranded. The article was labeled in part: "Flanders Standard Sutures and Ligatures * * * U. S. P. Surgical Catgut Sterile."

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth in such compendium since the sutures did not meet the test for sterility of solids, as required by that text, but were contaminated with living aerobic, sporulating bacilli.

It was alleged to be misbranded in that the statement on its label "U. S. P. Surgical Catgut Sutures Sterile" was false and misleading as applied to an article that was not sterile.

On January 8, 1943, Flanders-Day Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be resterilized under the supervision of the Food and Drug Administration.

974. Adulteration and misbranding of Sterilastic first-aid bandage. U. S. v. 126 Packages of Sterilastic First Aid Bandage. Decree of condemnation and destruction. (F. D. C. No. 8583. Sample No. 19313-F.)

On or about October 20, 1942, the United States attorney for the District of Maine filed a libel against 126 packages of Sterilastic first aid bandage at Portland, Maine, alleging that the article had been shipped on or about September 3, 1942, by Surgical Dressings, Inc., from Boston, Mass.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess.

The article was alleged to be misbranded in that the following statements appearing in its labeling, "Sterilastic * * * The gauze supplied with the Sterilastic may be used in any emergency," were false and misleading since such statements represented and suggested that the article was sterile and might be used in emergency first-aid injuries; whereas the article was not sterile but was contaminated with living micro-organisms.

On December 4, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

975. Adulteration and misbranding of Sani-Cross Waterproof First-Aid Treated Strips. U. S. v. 57 Cartons of Sani-Cross Waterproof First Aid Treated Strips. Default decree of condemnation and destruction. (F. D. C. No. 8598. Sample No. 9537-F.)

On October 19, 1942, the United States attorney for the Eastern District of Louisiana filed a libel against 57 cartons, each containing 36 packages, of the above-named product at New Orleans, La., alleging that the article had been shipped in interstate commerce on or about September 9, 1942, from New York, N. Y., by Universal Merchandise Co.; and charging that it was adulterated and misbranded. The article was labeled in part: "Distributed by Gero Products, Boston, Mass."

It was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, since by its form and nature it purported and was represented to be of such purity and quality that it would be suitable for use on cuts and other wounds, whereas it was not suitable for such use since it was contaminated with living bacteria.

It was alleged to be misbranded in that the statements appearing in its labeling, "Sani-Cross * * * First Aid Treated Strips * * * Wash wound with an antiseptic. Remove crinoline and apply gauze pad to the wound," were false and misleading since they represented and suggested that the article was a safe, sanitary, and appropriate bandage for first-aid use on minor cuts, wounds, and abrasions, whereas it was not a safe, sanitary, and appropriate bandage for such use in that it was contaminated with aerobic, anaerobic, or facultative anaerobic micro-organisms. It was alleged to be misbranded further in that it was in package form and its label failed to bear a statement of the quantity of the contents contained therein.

On December 14, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

976. Adulteration and misbranding of Sani+Cross Waterproof First Aid Treated Strips. U. S. v. 99¾ Gross Packages of Sani+Cross Waterproof First Aid Treated Strips. Default decree of condemnation and destruction. (F. D. C. No. 9325. Sample No. 44466-F.)

This product was contaminated with cocci and non-sporeforming rods.

On February 8, 1943, the United States attorney for the Southern District of New York filed a libel against the above-named product at New York, N. Y., alleging that the article had been shipped in interstate commerce on or about January 11, 1943, by the Gero Products, Inc., from South Boston, Mass.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be a drug, adhesive absorbent gauze (adhesive absorbent compress), the name of which is recognized in the United States Pharmacopoeia, an official compendium, since it consisted of an individual dressing prepared by affixing a number of layers of absorbent gauze to a strip of adhesive plaster, and its quality and purity fell below the standard set forth in such compendium since it was not sterile and did not meet the requirement of the sterility tests for solids as required by the Pharmacopoeia, but was contaminated with living bacteria and its difference in quality and purity from such standard was not plainly stated on its label.

It was alleged to be misbranded (1) in that the statements, "Sani+Cross First Aid Treated Strips for minor Cuts, wounds and abrasions," "Directions: Wash wound with antiseptic. Remove crinoline and apply gauze pad to wound,' were false and misleading since they represented and suggested that the article was a safe, sanitary and appropriate bandage for first-aid use in minor cuts, wounds, and abrasions, whereas it was not a safe and sanitary or appropriate bandage for such use; (2) in that the designation "Sani+Cross" appearing in the labeling was false and misleading since it created the impression that the article constituted a sterile and sanitary dressing, whereas it did not; and (3) in that it was in package form and its label failed to bear a statement of the quantity of the contents.

On March 10, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

977. Adulteration and misbranding of first-aid dressings. U. S. v. 183,464 Packages of First-Aid Dressings. Consent decree of condemnation. Product ordered released under bond to be brought into compliance with the law. (F. D. C. No. 8903. Sample Nos. 3416–F, 3451–F.)

On November 27, 1942, the United States attorney for the District of Kansas filed a libel against 183,464 packages of first-aid dressings at Kansas City, Kans., alleging that the article had been shipped on or about October 3, 1942, in interstate commerce, by Convenience, Inc., Greenville, S. C.; and charging that the article was adulterated and misbranded. The article was labeled in part: "Small First-Aid Dressing U. S. Army Carlisle Model Sterilized."

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, namely, "Sterilized."

It was alleged to be misbranded in that the following statements appearing on its label, "Sterilized * * * Red Color Indicates Back of Dressing. Put Other Side Next to Wound," were false and misleading since the statements represented and suggested that the article was sterile, whereas it was not sterile but was contaminated with aerobic and facultative anaerobic spore-bearing bacilli.

On November 28, 1942, Convenience, Inc., claimant, having consented to the entry of the decree, judgment of condemnation was entered and the product was ordered released under bond to be destroyed or brought into compliance with the law under the supervision of the Food and Drug Administration.

978. Adulteration and misbranding of fractionally distilled water. U. S. v. 171/25 Packages of Fractionally Distilled Water. Default decree of condemnation and destruction. (F. D. C. No. 8395. Sample No. 29413–F.)

On September 22, 1942, the United States attorney for the Southern District of Georgia filed a libel against the above-described product at Savannah, Ga., alleging that the article had been shipped on or about August 3, 1942, from Berkeley, Calif., by the Cutter Laboratories; and charging that it was adulterated and misbranded. The article was labeled in part: "Fractionally Distilled Water 50 c. c. A—4163 Sterile, Pyrogen-free, Safety Tested."

The article was alleged to be adulterated in that it purported to be and was represented as a drug, "Water for Injection," the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the standard set forth therein since it was not free from pyrogens.

It was alleged to be misbranded in that the statement "Pyrogen-Free, Safety Tested," appearing on its label, was false and misleading since it contained pyrogens and was not safe for injection.

On October 26, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

979. Adulteration of carbon tetrachloride. U. S. v. 2,736 Bottles of Carbon Tetrachloride. Decree of condemnation and destruction. (F. D. C. No. 9266. Sample No. 37441–F.)

On January 30, 1943, the United States attorney for the Eastern District of Virginia filed a libel against 2,733 bottles of carbon tetrachloride at Richmond, Va., alleging that the article had been shipped on or about December 22, 1942, from St. Louis, Mo., by National Package Drugs, Inc.; and charging that it was adulterated.

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the

standard set forth therein since this compendium establishes a standard for the permissible amount of carbonizable substances in carbon tetrachloride and provides that the residue remaining after evaporation of the drug is odorless, whereas the article contained more carbonizable substances than permitted by the United States Pharmacopoeia, and the residue remaining after evaporation had an odor resembling that of paint.

On April 9, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

980. Adulteration of ground white pine bark. U. S. v. 5 Bags of Ground White Pine Bark. Consent decree of condemnation and destruction. (F. D. C. No. 8410. Sample No. 17029–F.)

On September 24, 1942, the United States attorney for the District of New Jersey filed a libel against 5 bags, each containing 200 pounds, of ground white pine bark at Jersey City, N. J., alleging that the article had been shipped on or about March 6, 1942, from Asheville, N. C., by S. B. Penick & Co.; and charging that it was adulterated.

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in the National Formulary, an official compendium, and its purity fell below the standard set forth therein since it was contaminated with fragments of insects and quantities of such foreign matter as feather barbs, whole larvae, rodent hairs, and rodent excreta pellets, whereas the formulary provides that vegetable drugs are to be as free as practicable from insects or other live animal matter and other excretion.

On January 18, 1943, the claimant having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

HUMAN USE

981. Misbranding of R & R Ultra Violet Ray and Radiation Machine. U. S. v. August H. Riess (Lawndale Laboratories). Plea of not guilty. Tried to the court. Judgment of guilty. Fine, $250. (F. D. C. No. 8750. Sample No. 1001–F.)

On January 16, 1943, the United States attorney for the Southern District of California filed an information against August H. Riess, trading as Lawndale Laboratories, Lawndale, Calif., alleging shipment on or about June 29, 1942, from the State of California into the State of Michigan of one of the above-named devices which was misbranded.

Examination of this product showed that it was essentially a high voltage mercury vapor discharge tube. A spectrographic examination indicated that the gaseous discharge was in an ultraviolet transmitting tube, and that the character of the radiations from the discharge was primarily of the spectrum of mercury vapor. The intensity of ultraviolet light emitted was relatively of a weak order of magnitude and was observed to be some 50 times weaker than an ultraviolet lamp such as might customarily be used in normal routine of ultraviolet therapy.

The article was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of arthritis, acne, asthma, bronchitis, hay fever, gout, dropsy, constipation, indigestion, jaundice, cold hands and feet, anemia, carbuncles, boils, goiter, deafness, headache and eye trouble, lumbago, mumps, pleurisy, measles, low blood pressure, liver disease, hardening of the liver, neuritis, rheumatism, high blood pressure, nervousness, paralysis, palsy, locomotor ataxia, erysipelas, neuralgia, menopause, sprains, stiff neck, quinsy, stiff muscles, sinus disease, catarrh, varicose veins, psoriasis, fatigue, exhaustion, and female trouble; would be efficacious in treating affections of the prostate, thyroid glands, kidneys, bladder, heart, nerves, throat and tonsils, and disturbances of the sacro-iliac joint; would be efficacious to improve the circulation and bring about internal cellular massage; would build up the red corpuscles, improve the impoverished blood stream, increase glandular activity, and act as a natural tonic to the entire body; would stimulate increased activity in the glands creating the digestive juices; would produce an increase of the rapidity of the chemical changes from which life results; would relieve congestion in a natural manner

*See also Nos. 951, 954–958, 961–978.

and stimulate activity where metabolism is sluggish, and rebuild the body to healthfulness and happiness; would be invaluable to persons of advanced age or those whose occupations fail to give sufficient exercise; would stimulate bodily activity, improve digestion and elimination, restore bowel activity to normal, improve the circulation of the blood, and generally improve health, were false and misleading since it would not be efficacious for such purposes or accomplish the results claimed.

It was alleged to be misbranded further in that the statements appearing in its labeling, "Ultra Violet Rays * * * Are a Source of Vitamin D, are very beneficial to the upbuilding of the body, due to the difficulty in obtaining these Rays in a sufficient quantity under modern conditions, due to indoor occupations, and climatic conditions, our Laboratories have, after considerable research and experimentation, produced the R & R Ultra-Violet Ray and Radiation Machine," were misleading since such statements suggested and created the impression in the mind of the reader that the device would produce ultraviolet rays of sufficient intensity to produce in the body vitamin D in an amount sufficient to compensate in an important respect for the deficiency of vitamin D resulting from indoor occupations and unfavorable climatic conditions, whereas the device would produce ultraviolet rays of very weak intensity and would produce little, if any, vitamin D in the body.

On March 10, 1943, the defendant having entered a plea of not guilty, the case came on for trial before the court. At the conclusion of the testimony the court found the defendant guilty, and on March 22, 1943, imposed a fine of $250.

982. Misbranding of light bulbs. U. S. v. 240 Light Bulbs. Default decree of condemnation and destruction. (F. D. C. No. 8372. Sample No. 2063–F.)

Examination of these light bulbs showed that with the exception of an all-over decrease in the intensity of the light emanated from the bulb and the elimination of light in the ultraviolet range, their light emission characteristics were not different from those of the ordinary Mazda-type light bulbs.

On September 25, 1942, the United States attorney for the Northern District of Illinois filed a libel against 120 60-watt and 120 100-watt light bulbs at Chicago, Ill., alleging that the articles had been shipped in interstate commerce on August 5, 1942, from Toledo, Ohio, by the Save Electric Corporation; and charging that they were misbranded. The articles were labeled in part: (Shipping and individual cartons) "Doctors Say Verd-A Ray," and (shipping carton only) a design, a picture of a nurse.

The articles were alleged to be misbranded in that the statements and design appearing in the labeling, which represented and suggested that by their use in lieu of ordinary lamps the body supply of vitamin A would be conserved, therefore reducing eye and body fatigue, conserving energy, avoiding poor skin and poor vision, protecting the eyes, and aiding in the regulation of body metabolism, were false and misleading since the articles would not be efficacious for such purposes.

On May 5, 1943, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

983. Misbranding of rubbing compound and aspirin tablets. U. S. v. 49¼ Dozen Bottles of Rubbing Compound and 66 Dozen Packages of Aspirin Tablets. Decrees of condemnation and destruction. (F. D. C. Nos. 9094, 9097. Sample Nos. 5062–F, 5963–F.)

On December 30, 1943, the United States attorney for the Southern District of Illinois filed libels against 49½ dozen bottles of rubbing compound and 66 dozen packages of aspirin tablets at Peoria, Illinois, alleging that the articles had been shipped on or about August 29 and October 8, 1942, from St. Louis, Mo., by the Halitosine Co.; and charging that the articles were misbranded. The articles were labeled in part: "Domino Brand Superior Rubbing Compound With Isopropyl Alcohol," or "Domino 100 Tablets Aspirin."

Examination showed that the rubbing compound consisted essentially of water and isopropyl alcohol 23 percent, together with small amounts of boric acid, thymol, menthol, and methyl salicylate. The number of aspirin tablets per bottle varied from 94 to 105, averaging 96.4 tablets per bottle.

The rubbing compound was alleged to be misbranded in that the name of the article and the statements appearing on its label, "Superior Rubbing Compound With Isopropyl Alcohol * * * Use for massaging, sponging, after bathing, cooling and refreshing, for hospital and home," were misleading since such name and statements created the impression that the article was a product extensively marketed as rubbing alcohol compound, a product which contained approximately

70 percent of alcohol, or its equivalent, whereas the article was not such a product but was a preparation containing only 23 percent of isopropyl alcohol.

The aspirin tablets were alleged to be misbranded in that the statement on their label "100 Tablets Aspirin" was false and misleading since most packages contained less than 100 tablets each, and the average contents of the packages was less than 100 tablets.

On April 19, 1943, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

984. Misbranding of St. Joseph C–2223. U. S. v. 4½ Dozen and 4½ Dozen packages of St. Joseph C–2223. Decree of condemnation and destruction. (F. D. C. No. 9324. Sample No. 6587–F.)

On February 8, 1943, the United States attorney for the Eastern District of Missouri filed a libel against 4½ dozen 2-fluidounce packages, and 4½ dozen 6-fluidounce packages of the above-named product at St. Louis, Mo., alleging that the article had been shipped in interstate commerce on or about November 18, 1942, by the Plough Sales Corporation from Memphis, Tenn.; and charging that it was misbranded. The article was labeled in part: "St. Joseph Laboratories Division of Plough, Inc., New York, N. Y. Memphis, Tenn."

Examination showed that the article consisted essentially of water, alcohol 22.3 percent, sodium salicylate, approximately 81 grains per fluidounce, potassium iodide, approximately 15.4 grains per fluidounce, and glycerine, saccharin, anise, and extracts from plant drugs.

It was alleged to be misbranded in that the statement appearing in its labeling, "through its sedative action aids in lessening the discomfort and pain of Acute Rheumatic Fever and through its antipyretic effect, reduces fever," was false and misleading since such statement represented and suggested that the article was a sedative and was effective in the treatment of acute rheumatic fever, whereas it was not a sedative and was not so effective.

On May 14, 1943, no claimant having appeared and a total of 8⅓ dozen 2-fluidounce packages and 2⅔ dozen 6-fluidounce packages of the product having been seized, judgment of condemnation was entered and it was ordered that the product so seized be destroyed.

985. Misbranding of gauze bandages. U. S. v. 39 Dozen Packages of Gauze Bandages. Decree of condemnation and destruction. (F. D. C. No. 9250. Sample No. 28600–F.)

On January 27, 1943, the United States attorney for the Southern District of Florida filed a libel against 39 dozen packages of gauze bandages at Jacksonville, Fla., alleging that the article had been shipped on or about July 25 and October 1, 1942, from Long Island City, N. Y., by the Gotham Aseptic Laboratories; and charging that it was misbranded. The article was labeled in part: "Deane's Gauze Bandage * * * Sterilized."

The article was alleged to be misbranded in that the statement "Sterilized" appearing upon the package was false and misleading as applied to the article, since it was not sterile but was contaminated with living micro–organisms.

On March 4, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

986. Misbranding of gauze bandages. U. S. v. 600 Dozen and 120 Dozen Packages of Gauze Bandages. Default decree of condemnation. Product ordered released for sterilization and use by a public agency. (F. D. C. No. 8895. Sample No. 27321–F.)

On November 19, 1942, the United States attorney for the District of Puerto Rico filed a libel against 600 dozen packages of 1-inch and 120 dozen packages of 3-inch gauze bandages at San Juan, P R., alleging that the article had been shipped on or about June 30, 1942, from New York, N. Y., by the Universal Merchandise Co.; and charging that it was misbranded. The article was labeled in part: "Gauze Bandage * * * Sterilized after packaging Distributors Chatham Sundries Co. New York, N. Y."

The article was alleged to be misbranded in that the statement appearing in its labeling "sterilized after packaging" was misleading since it created the impression that the article was sterile, whereas it was not sterile but contaminated with living micro–organisms.

On January 25, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered released to be sterilized and thereafter used by the Emergency Medical Services (Civilian Defense) in Puerto Rico, conditioned that the bandages be sterilized before use.

987. Misbranding of Sani-Caps. U. S. v. 20 Boxes of Sani-Caps. Default decree of condemnation and destruction. (F. D. C. No. 9498. Sample No. 6634–F.)

On March 8, 1943, the United States attorney for the Southern District of Iowa filed a libel against 20 boxes of Sani-Caps at Davenport, Iowa, alleging that the article had been shipped in interstate commerce on or about November 12, 1942, from Rock Island, Ill., by Sani-Caps; and charging that it was misbranded.

Each carton of Sani-Caps contained a circular, 12 empty gelatin capsules, and a collapsible metal tube. Analysis of the contents of the tube showed that the article consisted essentially of glycerin and boric acid, with small amounts of an iodide and a silver compound.

The article was alleged to be misbranded in that the following statements appearing in its labeling: (Carton) "A Marvelous Treatment to preserve Health, Beauty, and Happiness. Instant Relief For Female Trouble," (circular) "Female troubles will be quickly relieved if the DIRECTIONS are followed. Fill a capsule and just before retiring insert into the vagina as far as possible. Allow the capsule to remain over night (advisable to wear napkin to prevent soiling of bed clothes); the next morning take a luke-warm water douche. If the ailment is serious, repeat during the day. In Most cases the first box shows results. If, in your case, Sani-Caps do not, don't get discouraged, as in cases of long standing it sometimes takes several boxes, but feel assured Sani-Caps will not fail. When your health and happiness has returned, don't forget this marvelous remedy, but adopt Sani-Caps for your personal hygiene. Use two or three capsules every week and your old troubles will never return. Sani-Caps are cheap insurance. To prevent INFECTION of disease use as above, giving the capsule time to thoroughly dissolve, 5 to 10 minutes. Afterwards use a douche if you desire," were false and misleading since such statements represented and suggested that the article was effective in the treatment and prevention of female troubles, whereas it was not so effective. It was alleged to be misbranded further in that its label failed to bear the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of its contents; and in that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient.

On April 14, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

988. Misbranding of Stero-Uteroids. U. S. v. 67 Cartons of Stero-Uteroids. Decree of destruction. (F. D. C. No. 9216. Sample Nos. 3548–F, 3549–F.)

On or about January 22, 1943, the United States attorney for the Western District of Missouri filed a libel against 67 cartons of Stero-Uteroids at Kansas City, Mo., which had been transported by the Ainsworth Specialty Co., alleging that the article had been manufactured by the Curts-Folse Laboratories, Kansas City, Kans., and transported to Kansas City, Mo., on or about August 21 and November 16, 1942; and charging that it was misbranded.

Analysis showed that the article consisted essentially of small proportions of zinc sulfate, plant material including alkaloid-bearing drugs, and a trace of iodine incorporated in a base of ichthammol and wool fat.

The article was alleged to be misbranded in that the statements "Stero-Uteroids * * * To be used only by or on the prescription of a physician," appearing in its labeling, were misleading since such statements represented and suggested that it was safe and appropriate for introduction into the uterus by, or as directed by, a physician, whereas it was not safe or appropriate for introduction into the uterus by a physician or any other person.

On April 2, 1943, the Ainsworth Specialty Co., Kansas City, Mo., claimant, having filed an answer to the libel, and later having withdrawn such answer and filed a confession of judgment with respect to the product, judgment was entered ordering that the product be destroyed and that the costs of the proceedings be assessed against the claimant.

989. Misbranding of Bio-Mineral. U. S. v. 76 Gross of Bio-Mineral. Decree of destruction. (F. D. C. No. 9270. Sample Nos. 3044–F, 3554–F.)

On or about February 18, 1943, the United States attorney for the Western District of Missouri filed a libel against 76 gross of Bio-Mineral at Kansas City, Mo., alleging that the article had been shipped in interstate commerce on or about December 21 and 22, 1942, and January 2, 1943, from Detroit, Mich., by the Bio-Mineral Products Co.; and charging that it was misbranded.

Examination showed that the article consisted essentially of a water solution of ferric sulfate (approximately 3.4 grains per teaspoonful) and smaller amounts of aluminum sulfate, calcium sulfate, magnesium sulfate, and a phosphate.

The article was alleged to be misbranded (1) in that the statements, designs, and devices appearing in its labeling which represented and suggested that it was effective in the treatment of rheumatism, constipation, weak kidneys, ailments of the colon leading to serious complications, piles, colitis, and appendicitis; that it was effective in keeping the colon clean and healthy and in eliminating accumulated poisonous matter therefrom; and that it was a solution of life-giving minerals, were false and misleading since it was not so effective and was not a solution of life-giving minerals; (2) in that the designation "Bio-Mineral," appearing in its labeling, was false and misleading since the article was not a life-mineral; (3) in that the statement appearing on its label, "A Natural Mineral Aid To be taken as a supplement for Mineral Deficiency," was false and misleading since the article would not supply, when taken in accordance with the directions, any mineral with the exception of iron, which would serve in any substantial manner as a supplement for mineral deficiency; and (4) in that the statement of chemical composition appearing on its label was misleading in the absence of a statement of the material fact that of the various ingredients mentioned none, except ferric sulfate, was of any material significance when the article was consumed in accordance with the directions appearing on the label.

On April 16, 1943, no claimant having appeared, judgment was entered ordering that the product be destroyed.

990. Misbranding of Viteen. U. S. v. 2,369 Jars and 929 Jars of Viteen. Consent decree of condemnation. Product ordered released under bond for relabeling. (F. D. C. No. 8862. Sample Nos. 1937–F, 1947–F.)

Examination showed that the article consisted primarily of dried skimmed milk with smaller proportions of egg yolk, a sugar, cereal products, calcium and phosphorus compounds, and flavoring material. It contained 27.8 percent protein, 10.3 percent mineral ash, 2.4 percent calcium, and 1.54 percent phosphorus.

On November 17, 1942, the United States attorney for the Northern District of Illinois filed a libel against 2,369 jars, 8 ounce size, and 929 jars, 18-ounce size, of Viteen at Chicago, Ill., alleging that the article had been shipped in interstate commerce within the period from on or about August 15 to October 27, 1942, from Rochester, N. Y., by L. N. LeBold & Co.; and charging that it was misbranded.

It was alleged to be misbranded in that the statements, designs, and devices appearing in its labeling which represented and suggested that the article constituted a suitable dietary supplement for use in restricted and unbalanced diets of various types, and whenever disturbances were apt to occur due to nutritional deficiencies, and that the use of the article would result in the reduction of weight, were false and misleading since the article did not constitute a suitable dietary supplement for use in such conditions, and its use would not result in the reduction of weight. It was alleged to be misbranded further in that the following statements appearing in its labeling "Analysis Each 100 grams of Viteen * * * contains: * * * Proteins * * * 31.96 Mineral Ash 13.28 Calcium 3.19 Phosphorus 1.79" were false and misleading since each 100 grams of the article did not contain the represented amounts of the ingredients named.

It was also alleged to be misbranded under the provisions of law applicable to foods, as reported in the notices of judgment on foods.

On December 1, 1942, L. N. LeBold & Co., claimant, having admitted the facts set forth in the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

991. Misbranding of double strength yeast extract and iron compound. U. S. v. 230 Bottles of Double Strength Yeast Extract and Iron Compound. Default decree of condemnation and destruction. (F. D. C. No. 8342. Sample No. 1103–F.)

On September 11, 1942, the United States attorney for the Western District of Michigan filed a libel against 230 bottles, each containing 75 tablets, of the above-named product at Grand Rapids, Mich., alleging that the article had been shipped in interstate commerce on or about June 3, 1942, from New York, N. Y., by the Columbia Medical Laboratories; and charging that it was misbranded.

A chemical examination showed that the article consisted essentially of calcium carbonate and a small quantity of yeast or yeast extract and sugar, and contained, per tablet, 0.64 grain of iron and 0.0022 grain of strychnine. A biological examination showed that the article contained not more than 10 International Units of vitamin B_1 per tablet.

It was alleged to be misbranded in that the statements appearing in its labeling, "Double Strength Yeast Extract * * * A Scientific formula combining the essential properties of Yeast Vitamines * * * Made With Brewer's Yeast. These tablets contain vitamins B and G which are known to stimulate the appetite," were false and misleading since they represented that the article, by reason of its yeast content, was a valuable source of the vitamins of yeast and that the vitamins B and G provided by the yeast would stimulate the appetite, whereas the article was not a valuable source of the vitamins of yeast in that it contained only small quantities of vitamins ordinarily present in yeast, and the vitamins B and G provided by the yeast would not stimulate the appetite. The article was alleged to be misbranded further in that it contained strychnine and its label failed to bear the name and quantity thereof.

On October 15, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

992. Misbranding of Dr. Wolff's Pro-cys-kera Ointment. U. S. v. 21 Jars and 2 Jars of Dr. Wolff's Pro-cys-kera Ointment. Decree of condemnation and destruction. (F. D. C. No. 8476. Sample No. 2093–F.)

Examination showed that this product consisted essentially of sulfur, salicylic acid, menthol, camphor, and ichthyol, incorporated in a base of saponifiable fat, lecithin, and cholesterin.

On October 1, 1942, the United States attorney for the Eastern District of Wisconsin filed a libel against 21 jars, each containing 1 ounce, and 2 jars, each containing 4 ounces, of the above-named product at Milwaukee, Wis., alleging that the article had been shipped in interstate commerce on or about September 3, 1942, from Chicago, Ill., by Dr. George F. Wolff; and charging it was misbranded.

The article was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it eradicated scalp disorders, and would nourish, strengthen, and promote the growth of the hair, penetrate the scalp and prevent infection, were false and misleading since it was not capable of eradicating scalp disorders and would not accomplish the results claimed.

On November 11, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

993. Misbranding of Formula "U." U. S. v. 73 6-Ounce Bottles and 18 12-Ounce Bottles of Formula "U." Default decree of condemnation and destruction. (F. D. C. No. 8680. Sample No. 18765–F.)

Examination showed that this product consisted essentially of water, carbolic acid, sugars, thymol, sage, alum, borates, and aromatic substances.

On November 10, 1942, the United States attorney for the Southern District of New York filed a libel against the above-listed amounts of Formula "U" at Newburg, N. Y., alleging that the article had been shipped on or about September 5, 1942, by Universal Antiseptic & Research Laboratories, Inc., Bristol, Tenn.; and charging that it was misbranded.

It was alleged to be misbranded in that the statements and cuts appearing in its labeling which represented and suggested that the article was an adequate treatment for major burns, varicose ulcers, and infected gums were false and misleading since the article was not an adequate treatment for such conditions.

On December 2, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

994. Misbranding of Adolorine. U. S. v. 31 Bottles of Adolorine. Default decree of condemnation and destruction. (F. D. C. No. 8922. Sample No. 31703–F.)

On November 25, 1942, the United States attorney for the Northern District of Ohio filed a libel against 31 bottles of Adolorine at Wooster, Ohio, alleging that the article had been shipped in interstate commerce on or about October 15, 1942, by John I. Wean from Eustis, Fla.; and charging that it was misbranded.

Examination showed that the article consisted essentially of mustard oil, oil of thyme, and a low-boiling petroleum oil.

It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it was an effective remedy for soreness of muscles and joints from strain or overwork, for sprains, bruises, relief for itching, and for nasal irritations, were false and misleading since the article was not an effective remedy for such conditions. It was alleged to be misbranded further in that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient since the

statement of composition which appeared on the label was given in Latin rather than in the English language.

On February 5, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

995. Misbranding of Ekzebrol. U. S. v. 12 Boxes and 5 Boxes of Ekzebrol. Default decree of condemnation and destruction. (F. D. C. No. 9138. Sample No. 14703–F.)

On January 5, 1943, the United States attorney for the Southern District of California filed a libel against 12 boxes, containing 6 ampuls each, and 5 boxes, containing 25 ampuls each, of Ekzebrol at Los Angeles, Calif., alleging that the article had been shipped in interstate commerce on or about October 23, 1942, by E. Tosse and Co. from Brooklyn, N. Y.; and charging that it was misbranded. The article was labeled in part: "Ekzebrol 10% Strontium Bromide in Sterile Saline Solution For Intravenous Injection."

The article was alleged to be misbranded in that the following statements appearing on the circular contained within the package: "Bromine has been given orally with success in support of external treatment of some forms of eczema, particularly those caused by nervous conditions. It has, however, been demonstrated that by parenteral injection its soothing influence is augmented and quickened to such an extent, that especially in acute cases, this treatment alone will suffice. In Ekzebrol, bromine is combined with strontium, the former acting on the nerve centers, the latter on the peripheral nerves. Strontium probably exerts also a vascular constringent effect," and "In Skin diseases caused by an abundance of chlorides, the chlorides become free after a bromine injection and are eliminated in a natural way," were false and misleading since strontium bromide when administered by parenteral injection does not have its soothing influence so augmented that it alone will be effective for acute cases of eczema; strontium bromide does not act on the nerve centers and peripheral nerves, and does not have a vascular constringent effect; and Ekzebrol will not be effective in the skin diseases caused by an abundance of chlorides.

On February 24, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

996. Misbranding of double strength solution of posterior pituitary. U. S. v. 1 Litre and 2 Bottles of Double Strength Solution of Posterior Pituitary. One lot tried to the court. Decrees of condemnation and destruction. (F. D. C. Nos. 7807, 7815. Sample Nos. 89506–E, 89507–E).

On June 26 and 29, 1942, the United States attorneys for the Southern and Eastern Districts of New York filed libels against 1 litre, at Brooklyn, N. Y., and 2 bottles, each containing 1 litre, of double strength solution of posterior pituitary, at New York, N. Y., alleging that the article had been shipped on or about November 18, 1941, by Armour and Co., Chicago, Ill.; and charging that it was misbranded.

The article was alleged to be misbranded in that the statements on its label, "Double Strength Solution of Posterior [or "Post"] Pituitary U. S. P XI," and "20 I. U. per cc." were false and misleading since the strength of the article was not double that of solution of posterior pituitary, as defined in the eleventh revision of the United States Pharmacopoeia, and was not 20 International Units per cc.

On February 5, 1943, Armour and Co. of Delaware, having appeared as claimant for the lot at New York and having denied the allegation in the libel with respect to misbranding and the case having come on for trial, the court, after hearing the evidence and the arguments of counsel, handed down the following memorandum opinion:

WILLIAM BONDY, *District Judge*: "Assuming that there was sufficient evidence of identity of the contents of the exhibits 1 and 3 in evidence, and of samples from which the tests were made by the claimant; and assuming that all the tests as to which evidence was given were properly made, as to which there is a very serious question, there is no proof that any of the tests disclosed more than 18.5 International Units. The Court believes that what might be called the tolerance of 20 percent either way was a tolerance allowed in determining whether the product complies with the requirements of the Food and Drug Act and whether it may be transported in interstate commerce. The Act does not authorize anyone to represent the strength of the solution in International Units in the absence of reasonable certainty on the part of the person making the representation.

"The label used by the claimant states specifically that the solution in the two bottles that were seized was 'Double Strength Solution Posterior Pituitary U. S. P. XI 20 I. U. per CC. For Manufacturing Use. Expiration date September 1943.'

"The Court understands that to be a representation that the solution had a strength of 20 International Units. The evidence of the experts on behalf of the government, whom the Court believes to be very well qualified, testified that it never was a double strength solution of 20 International Units, or, in other words, that it never exceeded at any time 16.2 Units. The claimant's experts, also men of unquestionable competence, testified that by the methods used by them in making their assays which they claim were used in compliance with the Pure Food and Drug Act, it at most equalled 18.5 Units.

"The only issue is whether the solution was properly labeled or branded. The evidence in the case shows that the solution never was a solution of 20 International Units.

"The Court is convinced that the claimant believed it was authorized to label the solution containing 18.5 as a 20 International Units solution, in view of the tolerance allowed by the Pharmacopoeia.

"The claimant was mistaken in believing that it was entitled to use that tolerance in making an absolute representation that the solution was one of 20 International Units.

"The label or representation was not correct. The two bottles were properly seized and must be condemned.

"There accordingly should be a decree in favor of the libellant, with costs."

On March 4, 1943, the court made the following findings of facts and conclusions of law:

WILLIAM BONDY, *District Judge:*

FINDINGS OF FACT

"1. That the two bottles, each containing one litre of an article labeled in part 'Double Strength Solution of Posterior Pituitary U. S. P. XI 20 I. U. per CC.' contained a solution of posterior pituitary the strength of which was not double the strength of solution of posterior pituitary U. S. P.

"2. That the two bottles described in finding No. 1 contained a solution of posterior pituitary which did not contain more than 18.2 International Units per cubic centimeter.

"3. That at no time since its manufacture by the claimant herein did the two bottles of solution of posterior pituitary herein contain 20 international units per cubic centimeter.

"4. The statement on the label of the product, 'Double Strength Solution of Posterior Pituitary, U. S. P. XI 20 I. U. per cc.' was false and misleading."

CONCLUSIONS OF LAW

"1. The product was misbranded while in interstate commerce.

"2. The product must be condemned."

On March 9, 1943, judgment of condemnation was entered against the lot at New York and it was ordered destroyed. On May 24, 1943, Pro-Medico Laboratories, Inc., Brooklyn, N. Y., claimant for the lot at Brooklyn, having filed an answer denying the allegation in the libel with respect to misbranding and subsequently having withdrawn its answer, judgment of condemnation was entered and the lot was ordered destroyed.

997. Misbranding of Thompson's Daily Vitamin and Mineral Ration. U. S. v. 8 Cartons of Thompson's Daily Vitamin and Mineral Ration. Consent decree of condemnation. Product ordered released under bond for relabeling. (F. D. C. No. 9040. Sample No. 13242–F.)

This product was represented in its labeling as supplying 1¼ times the minimum adult daily requirements of vitamins A and D, the minimum adult daily requirement of vitamin C and riboflavin, and 3 times the minimum adult daily requirement of vitamin B_1. It was also represented as containing specified amounts of vitamin B_6, niacin amide, pantothenic acid, and biotin, as well as calcium, phosphorus, iodine, iron, and copper.

On December 24, 1942, the United States attorney for the Western District of Washington filed a libel against 8 cartons, each containing 100 boxes, of the above named product at Seattle, Wash., alleging that the article had been shipped in interstate commerce on or about October 12, 15, and 20, 1942, from Los Angeles, Calif., by the William T. Thompson Co.; and charging that it was misbranded.

The article was alleged to be misbranded in that the statements appearing on the display card accompanying the article, "Vitamins For Vitality Improve your health! . . . Take the drudgery out of work . . . Put more pep in your play . . . Reduce colds . . . Cut down fatigue . . . Improve appetite and digestion . . . Build nervous stability . . . Prevent impaired eyesight due to Vitamin deficiencies . . . Build up your blood count . . . Prevent dental cavities, bleeding gums, due to deficiencies of Vitamins D, C, and Calcium," were false and misleading since such statements represented and suggested that the article would be effective for the purposes and conditions stated and implied, whereas it would not be so effective.

The article was also alleged to be misbranded under the provisions of law applicable to foods as reported in the notices of judgment on foods.

On January 14, 1943, William T. Thompson Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

VETERINARY USE*

998. Misbranding of Mineralized Bloat Stock Salt. U. S. v. 15 Sacks and 10 Sacks of Mineralized Bloat Stock Salt. Default decree of condemnation. Product to be disposed of by destruction. (F. D. C. No. 9039. Sample No. 7381–F.)

On January 6, 1943, the United States attorney for the District of South Dakota filed a libel against 15 50-pound sacks and 10 100-pound sacks of the above-named product at Sioux Falls, S. Dak., alleging that the article had been shipped in interstate commerce on or about November 6, 1942, from Sioux City, Iowa, by H. L. Johnson & Co.; and charging that it was misbranded. The article was labeled in part: "Mineralized Bloat Stock Salt with Potassium Iodide."

Analysis showed that the article consisted essentially of salt and calcium carbonate with small amounts of sulfur, sodium bicarbonate, sodium and magnesium sulfates, iron oxide, potassium iodide, phosphate, anise, and fenugreek.

The article was alleged to be misbranded in that the reference to "Bloat" in the name of the article, and the directions for the prevention and treatment of bloat in livestock, appearing in its labeling, were false and misleading since such statements represented and suggested that the article was effective in the prevention and treatment of bloat in livestock, whereas it was not so effective.

On February 15, 1943, no claimant having appeared and the court having found that the product was misbranded and should be destroyed, judgment of condemnation was entered and the marshal was ordered to dispose of the product.

999. Misbranding of Van-X Ointment. U. S. v. 8 Tubes and 38 Tubes of Van-X Ointment. Default decree of condemnation and destruction. (F. D. C. No. 8429. Sample No. 22489–F.)

On or about September 29, 1942, the United States attorney for the District of Delaware filed a libel against 8 $1.00-size and 38 $.25-size tubes of Van-X Ointment at Wilmington, Del., alleging that the article had been shipped on or about August 18, 1942, from Philadelphia, Pa., by the Totus Manufacturing Co.; and charging that it was misbranded.

Analysis of the article showed that it consisted essentially of a vegetable gum, small amounts of salicylic acid, phenol, sulfur, zinc oxide, and 13.5 percent of alcohol.

The article was alleged to be misbranded in that the following statement appearing in its labeling: (Tube) "Relief for Itch, Eczema, Skin Irritations—For All Breeds of Dogs * * * Apply to affected parts frequently until healed. In bad cases spread on sores and let dry. * * * Alcoholic contents not over 5%.," (carton) "For the Relief of Eczema, Itching, Scratching, and Skin Irritations. Also for mange, blotchy coats, falling hair * * * injuries * * * Stops itching immediately. * * * Active Ingredients * * * Alcoholic contents not over 5%," were false and misleading since the article would not be an effective relief for any known cause of eczema, itching, scratching, skin irritations, mange, blotchy coats, and all forms of injuries as was suggested and represented by such statements. It was alleged to be misbranded further in that the statement in its labeling, "Alcoholic contents not over 5%," was false and misleading since the article contained 13.5 percent of alcohol.

An April 12, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

*See also No. 961.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ACCURATE STATEMENT OF QUANTITY OF CONTENTS*

1000. Misbranding of tincture of iodine. U. S. v. 110 Dozen Bottles of Tincture of Iodine. Decree of condemnation. Product ordered delivered to a public institution. (F. D. C. No. 8612. Sample No. 22927-F.)

Examination showed that the average quantity of tincture of iodine contained in the bottles was 2.065 drams. The maximum amount found was 2.49 drams, and the minimum quantity was 1.72 drams.

On October 17, 1942, the United States attorney for the Eastern District of Pennsylvania filed a libel against 110 dozen bottles of tincture of iodine at Philadelphia, Pa., alleging that the article had been shipped on or about August 4, 1942, from New York, N. Y., by the Peerless Pharmacal Co.; and charging that it was misbranded in that its label failed to bear an accurate statement of the quantity of the contents. The article was labeled in part: "U. S. P. Tincture Iodine * * * 2¼ Dram."

On November 6, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a public institution.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 951–1000

PRODUCTS

SHIPPERS AND MANUFACTURERS

*See also Nos. 954, 956, 961, 976.

[1] Prosecution contested.

[2] Seizure contested. Contains opinion of the court, findings of fact, and conclusions of law.

[1] Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1944